CHAP

Community Health Accreditation Program, Inc.
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March 14, 2006

Patricia Harris
Executive Officer
California State Board of Pharmacy
1625 N. Market, Suite N219
Sacramento, CA 95834

RE: Re-Application for Board Approval under Senate Bill 293, Section 4127.1d

Dear Ms. Harris:

The Community Health Accreditation Program, Inc. (CHAP) is re-applying to California State Board of Pharmacy for approval to exempt pharmacies from licensure under requirements established by Senate Bill 293, Section 4127.1d of the Business and Professional Code.

Included is CHAP's current response to the evaluation factors identified by the Licensing Committee as required in section 4127.1. CHAP supportive documentation is attached as Appendix I-III. Included also is a cross-walk from CCR Section 1751 (revised) Sterile Compounding Regulations to CHAP CORE Standards 2004 and CHAP Pharmacy Standards 2004/1005.

Thank you for consideration of this re-application.

Please contact me if you need further documentation.

Sincerely yours,

Terry A. Duncombe, RN, MSHA
President & CEO

RE-APPLICATION TO THE CALIFORNIA STATE BOARD OF PHARMACY FOR APPROVAL TO EXEMPT PHARMACIES FROM LICENSURE UNDER REQUIREMENT ESTABLISHED BY TITLE 16 CALIFORNIA CODE OF REGULATIONS SECTION 1751 – REVISED (SECTION 4127, 4127.7 OF THE BUSINESS AND PROFESSIONS CODE)

SUBMITTED BY:
COMMUNITY HEALTH ACCREDITATION PROGRAM, INC. (CHAP)
1300 19th Street, Suite 150
Washington, DC 20036

Factor 1. Periodic Inspection

The Community Health Accreditation Program, Inc. (CHAP) conducts a full comprehensive site visit to pharmacies at least once every three years. Every standard for Core and Pharmacy, is assessed during these site visits. Based upon the performance of the pharmacy and the findings, particularly in the Quality Standards (Section II of each set of standards), the CHAP Board of Review may determine to require a return site visit within 6 -12 months to focus on and assess compliance with the required actions cited during the site visit. The Accreditation Process is described in the CHAP informational brochure, which is included as Appendix I.

Factor 2. Documented Accreditation Standards

CHAP accredits all types of pharmacies, including pharmacies that compound sterile products. CHAP currently uses two sets of standards to assess pharmacy services: Core 2004 (overall administrative standards) and Pharmacy 2004/2005 (service specific standards) Standards of Excellence. The Standards are included as Appendix II. Each of the standards contain language further requiring compliance with State and Federal statues governing pharmaceutical practice. Each pharmacy is assessed during a site visit for compliance with CHAP standards as well as federal and state-specific regulations. In addition, CHAP standards are consistent with the professional standards of practice as defined by the American Society of Health System Pharmacy and published in Best Practices for Health-System Pharmacy, ASHP, and referenced for assessment.

Subsequent to CHAP's initial application to the California State Board of Pharmacy in 2003, CHAP revised its pharmacy standards and formatted them in a tiered structure with basic standards applicable to all pharmacy services plus add-on standards with additional requirements applicable to specialized pharmacies such as infusion pharmacies. The CHAP 2004/2005 Pharmacy Standards are consistent with the intent of USP 797, incorporate requirements from Medicare Modernization Act, Part D, and are consistent with California State Board of Pharmacy Sterile Compounding Special Licensure regulations.

CHAP assesses standards in terms of "Met" or "Not Met." The standard must be met in full to be assessed as "Met." If any element of the standard is not met, the standard is assessed as "Not Met," and a "Required Action" is written for that Standard. Required Actions are actions which the organization is required to perform in order to achieve compliance with CHAP Standards. The Board of Review decision to accredit, deny accreditation or defer accreditation is based upon the number and types of Required Actions identified. CHAP does not use a scoring methodology for assessing compliance and determining accreditation decisions

An organization is **accredited** if the site survey findings provide evidence that the organization is in substantial compliance with CHAP standards. An organization is **deferred** in initial accreditation based upon evidence that the organization is not in substantial compliance with the CHAP Standards but has evidence that they possess the ability to come into substantial compliance within a reasonable time frame, not to exceed one year from the deferral date. A full site visit will subsequently be conducted to determine compliance with CHAP standards. An organization is **denied** initial accreditation based upon evidence that the organization is not in substantial compliance with the CHAP Standards and lacks adequate structure and function to correct the deficiencies in a timely manner. The organization has the option of re-initiating the application process six months from the date of the initial site visit. Other Board of Review accreditation decisions include **formal warning** and **termination.**

Factor 3. Evaluation of Surveyor's Qualifications.

CHAP requires pharmacy site visitors to have the following minimum qualifications:

1. Currently licensed Registered Pharmacist with a minimum Bachelor of science in pharmacy.
2. Five years experience in pharmacy management.
3. Current experience in community-based or infusion-based compounding pharmacy services.
4. Demonstration of strong analytical, consultative, conflict resolution, mediation and written and written and verbal articulation skills.
5. Demonstration of experience with an accreditation process.
6. Successful completion of a CHAP Site Visitor Training Program and four practicum site visits.

CHAP currently has four pharmacy site visitors with professional pharmacy experience ranging from 12 – 40 years, with clinical management experience ranging from 9 – 30 years, with one holding a Masters degree and two holding Doctor of Pharmacy degrees. Each one of CHAP's pharmacists is currently employed in active pharmacy services.

The CHAP Board of Review (BOR) has a pharmacist position appointed by the Board of Directors. That pharmacist is responsible for reviewing and assessing Pharmacy Site Visit Reports to assure consistent citation of pharmacy standards. The BOR Pharmacist is also responsible for assessing new or revised standards as part of the BOR and recommending adoption to the Board of Directors.
The CHAP Board of Directors (BOD) has a pharmacist member elected by the Board of Directors who is also a resource for pharmacy-industry related issues.

Factor 4. Acceptance by Major California Payors

CHAP is accepted by all California payors as well as all national payors.

Factor 5. Unannounced Inspection of California Accredited Sites

CHAP understands that the State Board of Pharmacy will conduct unannounced inspections of two or more California accredited pharmacy sites to assess for satisfactory compliance with California law and good professional practice.

Factor 6. Board Access to Accreditor's Report on Individual Pharmacies

CHAP provides a written report to each pharmacy following a site visit and review and determination by the Board of Review. Each of the pharmacies accredited by CHAP has a copy of the written report available on site.

Factor 7. Length of Time the Accrediting Organization Has Been Operating

CHAP has been accrediting organizations since 1965. CHAP was the first national accreditation organization to accredit community-based health organizations in the United States and was the first organization awarded deeming authority by CMS (formerly HCFA) for home health in 1992 and for hospice in 1999. CHAP Pharmacy Standards are recognized by JCAHO as being comparable in definition and expectations.

Factor 8. Ability to Accredit Out-of-State Pharmacies.

CHAP currently accredits organizations throughout the United States, Hawaii and Puerto Rico and is able to accredit pharmacies regardless of state of operation.

CHAP currently accredits 63 Pharmacies located in 23 states. CHAP has 16 pharmacies that have applied for accreditation and are in the process of contract execution or currently undergoing the self-study process.

Additional Questions:

1. What companies are accredited for Pharmacy by CHAP in California?

Accredited:
Factor Support Network Pharmacy, Inc., Camarillo

Applied for Accreditation:
Valu-Med Pharmacy, Anaheim
Pharmaco d/b/a Premier Infusion Care, Torrance

2. Is CHAP accreditation comparable to JCAHO ?

JCAHO has completed an evaluation of CHAP standards which resulted in their recognition of general comparability between the standards of our two organizations.

3. What is an example of an evaluation sheet and report?

The CHAP Site Visitor Work Book is used for evaluating compliance with the CHAP Standards. A Board of Review Site Visit Report is generated from the commendations, recommendations and required actions cited in the Site Visitor Work Book. The Board of Review reviews the Site Visit Report and completes a Summary Data Collection Tool in order to assure a logical and focused review of Site Visit Reports and to promote consistency in the interpretation of site visit findings by each reviewer. Consistency in the interpretation of site visit findings by the Board of Review drives the decision making process. A sample of the Site Visitor Work Book, the Board of Review Site Visit Report format and the Board of Review Summary Data Collection Tool are included as Appendix III.

COMMUNITY HEALTH ACCREDITATION PROGRAM, INC.
CROSSWALK OF CHAP PHARMACY STANDARDS 2004/2005 EDITION TO CALIFORNIA CODE OF REGUALATIONS
TITLE 16, SECTION 1751 (REVISED) and SECTIONS 4127, 4127.7
STERILE COMPOUNDING SELF-ASSESSMENT

CALIFORNIA CODE OF REGULATIONS SELF-ASSESSMENT DESCRIPTION *Title 16, Section 1751 (Revised)*	**CHAP STANDARD**
CCR 1751: COMPOUNDING AREA	
Clean room with walls, ceilings & floors are made of non-porous cleanable surfaces.	DIII.4a.3
Well ventilated.	DII.8a.6,8, DIII.4a.5
Laminar air flow hoods & clean room equipment are certified annually.	DIII.4f
Supplies stored in a manner which maintains integrity of an aseptic environment.	DIII.4a.7a DIII.4a.7c
There is a sink with hot and cold running water.	DIII.4a.2
There is a refrigerator of sufficient capacity to meet the storage requirements for all material requiring refrigeration.	DIII.4a.7b
CCR 1751.01: FACILITY AND EQUIPMENT STANDARDS FOR STERILE INJECTABLE COMPOUNDING FROM NON-STERILE INGREDIENTS	DIII.4a, DIII.4b.1
On or after July 1, 2005, the following shall apply to any pharmacy compounding sterile injectable products from one or more non-sterile ingredients.	
A ISO class 5 (class 100) laminar flow hood within an ISO class 7 (class 10,000) clean room (with positive air pressure differential relative to adjacent areas)	DIII.4a, DIII.4b.1
OR	
A ISO class 5 (class 100) clean room with positive air pressure differential relative to adjacent areas	DIII.4a, DIII.4b.1
OR	
A barrier isolator that provides a ISO class 5 (class 100) environment for compounding	DIII.4a, DIII.4a.1, DIII.4b.1, DIII.4e
No sterile injectable product prepared if it is known or reasonably should have known that the compounding environment fails to meet criteria specified in the pharmacy's written policies and procedures for the safe, compounding of sterile injectable drug products.	DII.7c.2, DII.8f.5, DIII.4b.5, DIII.4e, DIII.4g
Access to designated area or clean room limited to those individuals who are properly attired.	DII.8a.4, DII.8f.2, DIII.4g
All equipment used in the designated area or clean room must be made of a material that can be easily cleaned and disinfected.	DII.4a.3, DII.4a.7c, DII.8a.7
Exterior workbench surfaces and other hard surfaces in the designated area such as walls, floors, ceilings, shelves, tables and stools must be disinfected weekly and after any unanticipated even that could increase risk of contamination.	DII.7c.2, DII.8f1, DIII.4b2

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CALIFORNIA CODE OF REGULATIONS SELF-ASSESSMENT DESCRIPTION *Title 16, Section 1751 (Revised)*	**CHAP STANDARD**
CCR 1751.02: POLICIES AND PROCEDURES	
Written policies and procedures associated with the pharmacy's preparation and dispensing of sterile injectable products shall include but not be limited to:	DI.5
• Compounding, filling, and labeling of sterile injectable compounds	DI.5c.13, DI.5c.18-21
• Labeling of the sterile injectable product based on the intended route of administration and recommended rate of administration.	DII.5e.10, 11
• Equipment and supplies	DI.5c.14, 15
• Training of staff in the preparation of sterile injectable products	CI.5d.5, DI.5c.22-23, DII.8d
• Quality Assurance Program	DI.5e
• Record keeping requirements	CI.5c.9, CI.5h, CII.5a-g, DI.5c.17, DII.2b1f.1-7, DII.6a-b
• The ingredients and the compounding process for each preparation must be determined in writing before compounding begins and must be reviewed by a pharmacist	DII.2b1a4, DII.5c, DII.5d.2, DII.8f.3,4
• Written policies and procedures immediately available to all personnel involved in the compounding activities and Board of Pharmacy Inspectors	CI.5i, CIII.1f
• All personnel involved must read the policies and procedures before compounding sterile injectable products and any additions, deletions, and revisions to the written policies and procedures must be communicated to all personnel involved in sterile compounding	CI.5g.9a-c, CI.5i
Policies and procedures must address at least the following:	
• Staff competency evaluations	CIII.1i, DI.5c.22.23, DII.8f5, DIII.1c,1d
• Storage and handling of products and supplies	DI.5c1,3,9
• Storage and delivery of final product	DI.5c1,7,18, DIII.4c
• Process validation	DI.5c18, DII.7c2, DII.8f
• Personnel access and movement of materials into and near the compounding area	DII.8f2, DII.8a.1-10
• Use and maintenance of environmental control devices used to create the critical area for manipulation of sterile products (e.g. laminar air flow workstations, biological safety cabinet, class 100 clean room, and barrier isolation workstations).	DI.5e, DI.5c15, DII.8e

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CALIFORNIA CODE OF REGULATIONS SELF-ASSESSMENT DESCRIPTION *Title 16, Section 1751 (Revised)*	**CHAP STANDARD**
• Regular cleaning schedule for the controlled area and any equipment in the controlled area and the alternation of disinfectants (pharmacies subject to institutional infection control policy may follow that policy).	DI.5c.15, DII.8a.7, DII.8f
• Disposal of packaging materials, used syringes, containers, and needles to enhance sanitation and avoid accumulation in the controlled area.	DI.5e4, DII.8a9,10, DII.8c
• For sterile batch compounding, written policies and procedures must be established for the use of master formulas and work sheets and for appropriate documentation.	DII.6a.2,3
• Sterilization procedures exist (including documentation of sterilization results).	DI.5c18
• End-product evaluation and testing occurs.	DII.7c2, DIII.4b5
CCR 1751.2: LABELING REQUIREMENTS	
Labels to include telephone number of pharmacy (exemption: sterile injectable products dispensed for inpatients of a hospital)	DII.5e1
Name and concentration of ingredients contained in the product	DII.5e6
Instructions for storage and handling	DII.5e7, DIII.8d1-3
All cytotoxic agents shall bear a special label which states "Chemotherapy-Dispose of Properly"	DII.5e9
CCR 1751.3: RECORD KEEPING REQUIREMENTS	DII.6
There is an immediately retrievable patient medication profile for each patient.	DII.6
Pharmacies compounding sterile injectable products for future use shall also have records indicating the name, lot number, amount, and date on which the products were provided to the prescriber.	DII.5e, DII.6a2,3
Maintenance of records for three years to include:	CI.5h2,3
• Training and competency evaluation of employees in sterile product procedures.	CI.5h8, CIII.1g13
• Refrigerator and freezer temperatures are monitored and documented.	DII.4a,b,c
• Certification of the sterile compounding environment occurs on a regularly scheduled basis according to written policies and procedures.	DII.6a3d, DIII.4b4, DIII.4f
• Other facility quality control logs specific to the pharmacy's polices and procedures are maintained (e.g. cleaning logs for facilities and equipment)	DIII.4b1-5
• Inspection records for expired or recalled pharmaceutical products or raw ingredients exists.	DI.5c25, DII.8c1
• Preparation records including the master work sheet, the preparation work sheet and records of end-product evaluation	DII.6a3d, DII.4a-c, DII.7c2, DIII.4b5

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CALIFORNIA CODE OF REGULATIONS SELF-ASSESSMENT DESCRIPTION *Title 16, Section 1751 (Revised)*	**CHAP STANDARD**
CCR 1751.4 ATTIRE	
When preparing cytotoxic agents, gowns and gloves are worn	DII.8a.4
Clean room garb consists of a low-shedding coverall, head cover, face mask, and shoe covers must be worn inside the designated area at all times.	DI.5e, DI.5e.4
Clean room garb must be donned and removed outside the designated area	DI.5e, DI.5e.4
Hand, finger and wrist jewelry must be removed. If jewelry cannot be removed, the jewelry must be thoroughly cleaned and covered with a sterile glove	DI.5e, DI.5e.4
Head and facial hair must be kept out of the critical area or be covered	DI.5e, DI.5e.4
Protective gloves made of low-shedding materials are required	DI.5e, DI.5e.4
Note: Requirements may not apply if a barrier isolator is used to compound sterile injectable products from one or more non-sterile ingredients.	
CCR 1751.5: TRAINING OF STAFF, PATIENT AND CAREGIVER	
Consultation shall be available to the patient and/or primary caregiver concerning proper use of sterile injectable products and related supplies furnished by the pharmacy	DII.5i, DII.5j, DII.8d
The pharmacist-in-charge shall ensure all personnel engaged in compounding sterile injectable drug products shall have training and demonstrate on-going competence in the safe handling and compounding of sterile injectable drug products including cytotoxic agents.	CIII.1l, DIII.1c, DIII.1d, DIII.1g
Records of training and demonstrated competence shall be available for each individual and shall be retained for 3 years beyond the period of employment.	CI.5h.8
Pharmacies must have an established and follow a written program of training performance evaluation designed to ensure that each person working in the designated area has the knowledge and skills necessary to perform their assigned tasks properly.	DIII.1g
The program of training and evaluation shall address the following: aseptic technique, pharmaceutical calculations/terminology, sterile products compounding documentation, quality assurance procedures, aseptic preparation procedures, proper gowning and gloving techniques, general conduct in the controlled area, cleaning/sanitizing and maintaining equipment used in the controlled area, sterilization techniques, container, equipment and closure system selection.	DII.8f, DIII.1b10, DIII.1c, DIII.1d

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Each person assigned to the controlled area must successfully complete practical skills training in aseptic technique and aseptic area practices.	DII.8a, DIII.1b.6,10, DIII.1g
Evaluations must include written testing and a written protocol of periodic routine performance checks involving adherence to aseptic area policies and procedures.	DIII.1d.1-5
Each person's proficiency and continuing training needs must be reassessed every 12 months.	DIII.1c.2, DIII.1d
Results of staff assessments must be documented and retained in the pharmacy for three years.	CIII.1g.8,9, CIII.1i.1-4
CCR 1751.6: DISPOSAL OF WASTE MATERIAL	
Pharmacies compounding sterile injectable products shall have written policies and procedures for the disposal of infectious materials and/or other materials containing cytotoxic residue.	CII.7e.4, CII.7e.5, DI.5e.4, DII.8a.10
Procedures shall include cleanup of spills and shall be in conformance with local health jurisdiction.	DII.8c.2, DIII.4a
CCR 1751.7: QUALITY ASSURANCE AND PROCESS VALIDATION	
Each pharmacy shall have a documented on-going quality assurance program that monitors personnel performance, equipment, & facilities.	DII.5e, DII.7, DII.8a.1-10, DII.8c, DII.8f
The end product shall be examined on a periodic sampling basis as determined by the pharmacist-in-charge to assure that the product meets required specifications.	DI.5c.18, DII.7c, DIII.4b.5
The quality assurance program shall include:	
• Cleaning & sanitization of the parenteral medication preparation area.	DII.8a7, DII.8d.1, DIII.1f.1-5, DIII.4b.1-5
• Written documentation that the end product has been tested on a periodic sampling basis for microbial contamination & steps taken in the event that testing for contamination proves positive.	DII.7b, DII.7c.2, DIII.4b.5
• The storage of compounded parenteral products in the pharmacy and periodic documentation of refrigerator temperature.	DIII.4c, DII.8d.2
• Steps taken in the event of a drug recall.	DI.5c.25, DII.8c.1
• Written justification of the chosen expiration date for compounded injectable drug products.	DII.5e.11
Process Validation:	
• Each individual involved in the preparation of sterile injectable products from one or more non-sterile ingredients must successfully complete a validation process before being allowed to prepare sterile products.	DII.8f.2,4,5, DIII.1b.10, DIII.1d.1-5, DIII.1c

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• The validation process shall be carried out in the same manner as normal production, except that an appropriate microbiological growth medium is used to test the sterility of the final product.	DII.8f.5, DIII.4e.1
• The same personnel, procedures, equipment, and materials are involved.	CIII.1i.1-4, DII.8f.1-5
• Completed medium samples must be incubated.	DIII.7c.2, DII.8f.5
• If microbial growth is detected, then the sterile preparation process must be evaluated, corrective action taken, and the validation process repeated.	CII.6d, CII.6e, CII.6g, DII.7c.2
• Personnel competency must be revalidated at leaset every 12 months, whenever the quality assurance program yields an unacceptable result, or whenever improper aseptic techniques are observed.	DIII.1d.1-5
• The validation and revalidation process must be documented.	CIII.1g.8a-b,15, CIII.1i.4, DII.6a.3d
CCR 1751.9: REFERENCE MATERIALS	
There must be current and appropriate reference materials regarding the compounding of sterile injectable products located in or immediately available to the pharmacy.	DI.2d, DIII.1g

CHAP Accreditation Is A Process Not An Event

The 4 Steps to the CHAP Accreditation Process

Step 1 - Application and Contract

- Organization completes the Application for Accreditation and submits to the CHAP office.
- CHAP first determines the organization's eligibility for accreditation.
- CHAP then determines the number of site visit days necessary to assess the organization.
- Based on the information provided, CHAP establishes the fee for accreditation.
- CHAP develops a contract for accreditation which outlines the duties and responsibilities for both parties.

Step 2 - Self Study

- The Self Study is a tool which allows the organization to do a comprehensive internal evaluation against the CHAP Standards of Excellence.
- Organization has three to six months from the date of the signed contract to submit the completed self study.

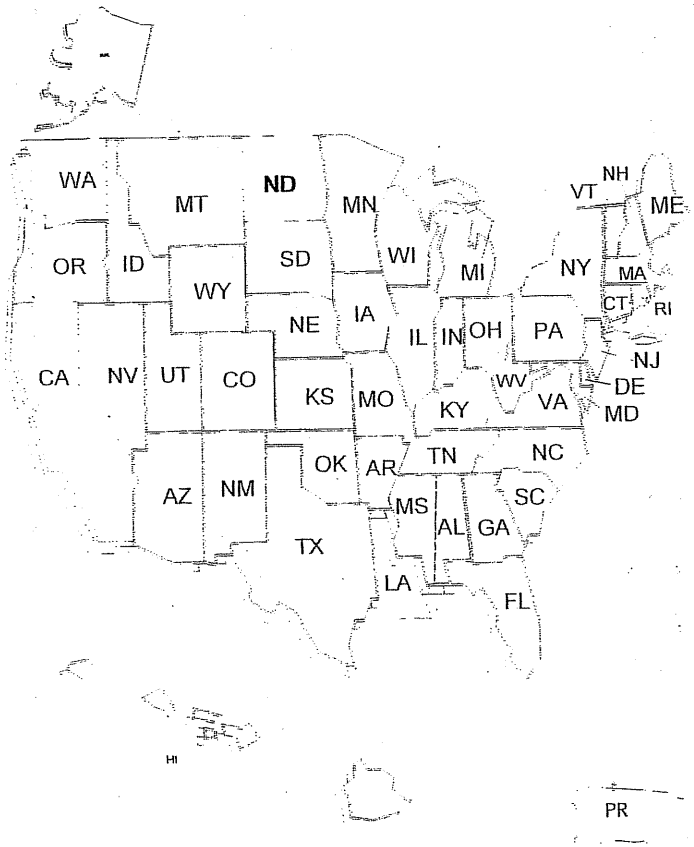
Step 3 - Site Visit

- Announced or in some cases must be unannounced
- Length of site visit & composition of the team is contingent upon the organization's size, complexity of products, and services provided
- CHAP site visitors are health care professionals with 5 or more years of experience in their area of expertise

Step 4 - Determination of Accreditation Status

- Board of Review (BOR) members are industry experts
- Review all site visit reports for accuracy and findings
- Determine accreditation status for all organizations

Service Areas



Note: Map not to scale

For additional information, please feel free to contact CHAP at:

Phone: 800-656-9656
E-mail: info@chapinc.org
Web Site: www.chapinc.org

COMMUNITY HEALTH ACCREDITATION PROGRAM

CHAP

Really Only One Choice

The First Nationally Recognized Community Based Accreditation Organization

Community Health Accreditation Program, Inc. (CHAP), the first national accrediting organization to receive "Deeming Authority" from CMS, was established in 1965 as a joint venture between American Public Health Association (APHA) and the National League for Nursing (NLN). In 1988, CHAP became a wholly-owned subsidiary of the NLN and in 2001 became an independent non-profit corporation governed by a voluntary Board of Directors.

Members of the CHAP Board of Directors represent consumers, providers, and experts in the home and community health care industry.

The CHAP philosophy assures the availability of quality home and community based health care through the voluntary commitment to accreditation by the applicant organizations. This is essential as home and community health care becomes the centerpiece of the health care industry. It is CHAP's firm belief that the accreditation process should separate excellent organizations and programs from those meeting only minimal standards.

Accreditation Plays An Important Role In Today's Healthcare System

CHAP accreditation publicly certifies that an organization has voluntarily met the highest standards of excellence for home and community based health care. CHAP has **Standards of Excellence** driven by considerations of quality, client outcomes, adequate resources, and long-term viability. The CHAP goal is to assist all types of community based health care organizations to:

- Strengthen internal operations
- Promote continuous quality improvement
- Promote positive client outcomes
- Promote consumer satisfaction
- Cost effectively meet organizational needs
- Maintain organizational viability
- Assure public trust in community based health care services and products

Eligibility For Accreditation:

- The organization must have legal authority to operate.
- Provide one or more of the services or product lines listed on the next page.

CHAP accredits over 1,500 community based organizations.

Programs Accredited CHAP Standards of Excellence

The CHAP **Standards of Excellence** provide guidance and reality-based criteria for the evaluation of an organization. These criteria are based on four key "underlying principles" which drive each set of CHAP standards. The four guiding principles are:

1. The organization's structure and function consistently supports its consumer oriented mission.
2. The organization consistently provides high quality services and products.
3. The organization has adequate human, financial, and physical resources to accomplish its stated mission.
4. The organization is positioned for long-term viability.

CHAP maintains standards of excellence and provides accreditation for the following services:

- Home Health
- Hospice
- Home Medical Equipment
- Home Infusion Pharmacy
- Infusion Therapy Nursing
- Public Health
- Community Nursing Centers
- Private Duty Services
- Home Care Aide Services
- Supplemental Staffing Services

CORE

STANDARDS OF EXCELLENCE

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INTRODUCTION TO CHAP CORE STANDARDS

The Community Health Accreditation Program, Inc. (CHAP, Inc.) is an independent, non-profit accrediting body for community based health care organizations. The types of organizations accredited include: home health, hospice, public health, home care aide services, private duty services, supplemental staffing services, infusion therapy nursing, home medical equipment, pharmacy services, and community nursing centers.

This "first" accrediting body for community based health care organizations in the United States dates back to 1965. A joint venture between the American Public Health Association (APHA) and the National League for Nursing brought to fruition the futuristic view of their respective membership that accreditation was the needed mechanism to recognize excellence in community health practice. In 2001, CHAP became an independent corporation with the purpose of using the accreditation process to elevate the quality of all community-based health care in the United States.

The CHAP accreditation process utilizes the "CHAP Standards of Excellence" that are driven by considerations of management, quality, client outcomes, adequate resources and long term viability.

The goal is to assist all types of community-based health care organizations to:

- Strengthen internal operations
- Promote continuous quality improvement techniques and systems
- Promote consumer satisfaction
- Affirm public trust
- Meet community health needs in a cost efficient and effective manner
- Maintain the viability of community health practice nationwide

CHAP, Inc. is committed to ensuring that home and community based health care providers adhere to the highest standards of excellence and that they maintain compliance with the current standards. Ongoing professional assistance and guidance provided by CHAP promotes continuous organizational self-improvement.

CHAP Accreditation publicly certifies that an organization has voluntarily met the highest standards of excellence for home and/or community based health care. Additional benefits of Accreditation by CHAP, Inc. include management consultation of the highest quality, access to a broad network of professional resources, and guidance critical to building intra- and inter-organizational collaboration and strength.

Currency and Relevance of Standards

In keeping with its goal of elevating the quality of all community health care in the United States, CHAP, Inc. continually reviews and revises the "Standards of Excellence" to assure currency with the community health care industry. CHAP standards place a strong emphasis on organizational management and client outcomes. They are to be used as a blueprint to build and maintain a highly sophisticated home or community health care organization, thus assuring the viability of the organization.

The 2004 Edition revisions are designed to:

- Establish standards of excellence for a wide variety of home and community-based health care organizations and programs
- Promote ease of application, interpretation and use of standards
- Emphasize the importance of the interests and rights of individual and group consumers of home and community-based health care services
- Strengthen the long-term viability of all types of community-based health care organizations
- Advance the recognition of the importance of home and community-based health care organizations as integral components of the national health care delivery system

The re-engineered CORE Standards of Excellence address the scope and complexity of community-based health care providers in today's health care arena, are generic, and apply to all services and programs accredited by CHAP.

The core standards are used in conjunction with service specific standards to ensure compliance with:

- Federal, state and local regulatory requirements
- Regulatory requirements that address the health and safety of employees and clients

The service specific standards address requirements additional to Core which are unique to the specific service or industry.

Additional Requirements for Medicare-Certified Home Health and Hospice Services

CHAP has received authority from the Centers for Medicare and Medicaid Services (CMS) to deem certified home health services and certified hospice services to be in compliance with the Conditions of Participation (COPs). CHAP's Core/Home Health Standards and CHAP's Core/Hospice Standards contain standards which include the intent of the Medicare COPs for home health and hospice.

The home health agency that elects to receive Medicare Certification through deeming authority from CHAP must comply with CFR 484 Medicare Conditions of Participation: Home Health Agencies. See Appendix I HH for a full text of the home health regulations and a cross walk to the CHAP Standards.

The hospice organization that elects to receive Medicare Certification through deeming authority from CHAP must comply with CFR 418 Medicare Conditions of Participation: Hospice. See Appendix I H for a full text of the hospice regulations and a cross walk to the CHAP Standards.

Underlying Principles

I. Structure and Function
II. Quality
III. Resources
IV. Long Term Viability

Four key "Underlying Principles" (UP) continue to drive each set of the CHAP Standards of Excellence. Sub-categories in each section further define the content.

UP I. THE ORGANIZATION'S STRUCTURE AND FUNCTION CONSISTENTLY SUPPORTS ITS CONSUMER ORIENTED MISSION

A. Statement of Mission
B. Organizational Structure And Functional Mechanisms
C. Organizational Relationships/Chart
D. Administrative Authority and Responsibility
E. Organizational Policies
F. Communication
G. Ethical Issues
H. Research Initiatives

UP II. THE ORGANIZATION CONSISTENTLY PROVIDES HIGH QUALITY SERVICES AND PRODUCTS.

A. Business and Clinical Practices
B. Client Access to Care, Services and Products
C. Prioritization of Care Delivery
D. Coordination, Planning, Implementing, Monitoring, and Evaluating Care and Services Provided
E. Client Records
F. Performance Improvement
G. Safety of Employees and Clients
H. Complaints

UP III. THE ORGANIZATION HAS ADEQUATE HUMAN, FINANCIAL, AND PHYSICAL RESOURCES TO ACCOMPLISH ITS STATED MISSION AND PURPOSE.

A. Human Resources Support Workload Demand
B. Contracts
C. Financial Management
D. Financial Information System
E. Physical Facilities
F. Management Information System

UP IV. THE ORGANIZATION IS POSITIONED FOR LONG TERM VIABILITY.

A. Strategic Planning
B. Annual Evaluation of the Organization

As you study and apply these standards to your own organization, give consideration to the following "*THEMES*" that flow through all sections of the CHAP Standards of Excellence and Self Studies.

Composition of a Standard

Each standard statement may be comprised of four (4) parts.

1. Standard statement - A blueprint for success that recognizes excellence
2. Criterion - A statement that defines in detail the requirements of the standard
3. Element - A component of each criterion that delineates requirements
4. Sub-element – Additional statements that provide more definition of selected elements.

Examples

Standard:.....CI.1
Criterion:.....CI.1a
Element:.....1)
Sub element:.....(a) (not all standards have sub-elements)

Main Sources of Evidence

D = Documents
I = Interviews
O = Observations
S = Surveys

Substantiation of Findings

Clarification
Verification
Quantification

Evidence Guidelines

The Standards are formatted with relevant Evidence Guidelines on pages opposite the standards. The evidence guidelines are not standards or criteria. They are intended to provide guidelines and examples of evidence to the organization and to the CHAP site visitor which may be used to determine organizational compliance with the standards. The letter preceding each evidence guideline identifies one of four sources of information to be used by the site visitor in the accreditation process: D, I, O, S.

The Site Visit Report

The Site Visit Report is a legal document that states the level of compliance with the CHAP Standards of Excellence. The composition of the report includes a brief organizational profile, statements of organizational strengths and challenges and the written citations.

Citations include:

Commendation: A statement indicating that the organization has significantly exceeded the requirements of a specific standard or criterion.

Required Action: A statement indicating partial or total non-compliance with a CHAP standard or criterion. Organizations are required to make changes to comply with CHAP standard or criterion.

Recommendation: A statement of advisement that identifies a potential problem related to a standard or criterion that may increase in scope and severity if not addressed. Organizations are not required to make changes but should give serious consideration to the recommendation.

Medicare Deficiencies for Home Health and Hospice Organizations:

Tag Items:

Identifiers used by CMS that indicate non-compliance with one or more Medicare Conditions of Participation or Standards are defined as Tag Items.

Tag Item designation applies only to Home Health and Hospice Organizations.

- G-Tags are specific to Home Health
- L-Tags are specific to Hospice

Tag Item designations are used in the Site Visit Report and on all CMS required documents for deemed organizations.

THE PROCESS REQUIRED TO ACHIEVE CHAP ACCREDITATION

CREATES PROFESSIONAL REWARDS FOR YOUR ORGANIZATION.

Abbreviations

Common abbreviations used throughout the CORE Standards include:

ADA Americans with Disabilities Act
Admin. Administration

CDC Centers for Disease Control and Prevention

FDA Federal Drug Administration

GB Governing Board

HBV Hepatitis B Vaccine

MC Medicare
MD Medicaid
MDA Medical Device Act
Mgmt. Management

N.B. "Note Well"

OSHA Occupational Safety and Health Act

P&Ps Policy(ies) and Procedure(s)

TO Table of Organization
TB Tuberculosis

CI.

THE ORGANIZATION'S STRUCTURE AND FUNCTION CONSISTENTLY SUPPORT ITS CONSUMER ORIENTED PHILOSOPHY, MISSION AND PURPOSE

LEGEND:

D - DOCUMENTATION
I - INTERVIEW
O - OBSERVATION
S - SURVEY

CI.1

D: Current Mission statement includes a consumer focus and orientation to quality. (CI.1)

D: Consumers are defined as individuals, groups and communities. (CI.1)

D: Governing body minutes document actions taken on the Mission:
a) Review and approval at least every 36 months
b) Revisions and updates as applicable
(CI.1b)

CI.1 Published mission statements clearly identify a commitment to providing high quality services and products which address consumer needs as an organizational priority.

CI.1a Programs and services provided reflect the organization's written mission.

CI.1b The mission statement is reviewed, revised as indicated, and approved by the governing body at least every 36 months.

LEGEND:

D - DOCUMENTATION
I - INTERVIEW
O - OBSERVATION
S - SURVEY

CI.2

D: **Legal documents, specific to the organization, delineate applicable elements of CI.2b which may include: partnership agreement, articles of incorporation, bylaws, state charter, state licensure, tax license, trade name registration, business license, amendments, medicare certification and special waivers.**

D: *Note: Governing Body may be a governmental entity.(CI.2c)*

D & I: **Name, address, credentials and professional/business affiliation of each member is identified. (CI.2d)**
Note: Owner/Operator of a business may constitute the governing body. Governmental Boards of Health may be advisory in nature and/or may be elected or appointed officials.

D &I: **New member orientation is validated in writing. Governing body members describe the orientation experience and articulate key issues affecting the organization. (CI.2e)**
Note: Independent owner(s) may only have principal(s) as governing body, and orientation in CI.2e may not apply.

I: **Governing body members articulate responsibilities and describe the types of actions taken by the board. (CI.2f)**
Note: Selected elements may not apply to owner/operator businesses, i.e., selecting the chief administrator.

D: **Current signed and dated annual disclosure statements are on file for all governing body members and executive staff. (CI.2g)**

D &I: **Governing body members confirm adherence by governing body members to legal documents which may describe notice of scheduled and special meetings, attendance requirements at meetings, appointment of officers, terms of office, committee structure and function, quorum determination. (CI.2h)**

D: **Governing body minutes reflect agenda items, discussion, and action taken. (CI.2i)**
Note: Closed sessions are to be documented and distributed/filed per organizational policy.

Note: The Medicare Certified home health agency must comply with CFR 484.12, 484.12(c), 484.14(b), 484.14(i), 484.16, 484.52. See Appendix I HH for a full text of the regulations and a cross-walk.

Note: The Medicare Certified hospice organization must comply with CFR 418.50(c), 418.52, 418.72. See Appendix IH for a full text of the regulations and a crosswalk.

CI.2	The organization has the structure and functional mechanisms necessary to support and accomplish its stated mission.

CI.2a The organization has the legal authority to operate and is in compliance with local, state and federal regulations.

CI.2b The applicable governance structure is defined in legal documents specific to the organization.

CI.2c An identified governing body assumes full legal authority, responsibility, and accountability for organizational performance; appoints a qualified administrator and designates advisory group membership as applicable.

CI.2d The governing body is made up of individuals with relevant expertise, business acumen, and professional relationships specific to the stated mission of the organization.

CI.2e Governing body members are oriented to the organization and are knowledgeable and responsive to key issues affecting the organization.

CI.2f The governing body carries out responsibilities specific to the organization including:

1) Establishing policies consistent with organizational mission
2) Approving new and/or revised policies and procedures as indicated and necessary
3) Holding management accountable for the fiscal solvency of the organization and adequacy of financial resources
4) Approving budgets and capital expenditures
5) Selecting and evaluating the chief administrator
6) Evaluating organizational performance
7) Developing and approving strategic plan
8) Reviewing legal and business documents in light of real or potential changes to the organization on a periodic basis but not less frequently than every 36 months:
   (a) Articles of incorporation
   (b) Bylaws
   (c) Legal agreements

C1.2g Annually, the members of the governing body and executive staff provide written disclosure of all professional or personal relationships or interests, direct or indirect that might present a conflict of interest. Statements are on file in the office.

CI.2h The governing body complies with organizational bylaws or other legal documents.

CI.2i Accurate, complete, and signed minutes are kept of all official meetings of the governing body, document actions taken, are distributed in accordance with organizational policy, and are retained for minimum of five (5) years or consistent with state regulations.

LEGEND:

D - DOCUMENTATION
I - INTERVIEW
O - OBSERVATION
S - SURVEY

CI.3

D:	A current organizational chart reflects lines of authority and accountability for all personnel. (C1.3a)
D:	Amendments to the organizational chart are documented as applicable. (CI.3b)
I:	Staff members are familiar with the organizational chart and state their individual lines of authority and accountability. (CI.3c)

Note: The Medicare Certified home health agency must comply with CFR 484.12, 484.14. See Appendix I HH for a full text of the regulations and a cross-walk.

CI.3	Intra-organizational relationships are clearly defined.

CI.3a A current organizational chart delineates the lines of authority and accountability of all personnel.

CI.3b The organizational chart is reviewed and changed as needed.

CI.3c Personnel understand and use the organizational structure as outlined in the organizational chart.

LEGEND:

D - DOCUMENTATION
I - INTERVIEW
O - OBSERVATION
S - SURVEY

CI.4

D: **Current job descriptions are on file for administrative and management positions. (CI.4a, b)**

D: **CEO/Administrator/Management resumes validate experience, knowledge, and qualifications required for the job. (CI.4b)**

Note: This standard may pertain to the Chief Health Care Administrator in Public Health Organizations.

D: **Written policy and procedure defines assignment of administrative responsibilities in the absence of the CEO/Administrator. (CI.4c)**

I: **Designated alternate to the CEO/Administrator understands his/her role and describes experiences specific to the alternate role. (CI.4c)**

I: **CEO/Administrative and Management personnel describe their respective areas of responsibility. (CI.4d)**

Note: The Medicare Certified home health agency must comply with CFR 484.12, 484.12(a), 484.14(c). See Appendix I HH for a full text of the regulations and a cross-walk.

Note: The Medicare Certified hospice organization must comply with CFR 418.56(c). See Appendix IH for a full text of the regulations and a crosswalk.

CI.4	Authority and responsibility for overall administration and management is vested in qualified individuals.

CI.4a The chief executive/administrator's credentials include appropriate industry experience and knowledge of applicable local, state and federal laws.

CI.4b Qualifications for administrative and management positions are clearly defined in writing and are consistent with the scope of responsibility and the complexity of the organization, and administrative and management personnel have equivalent combinations of education, training and experience to qualify for their assigned responsibilities.

CI.4c A qualified individual is designated in writing to be administratively responsible in the absence of the chief executive/administrator.

CI.4d Administrative and management responsibilities are clearly defined and delegated as specified and include:

1) Organizing and directing the organization's ongoing operations to assure the availability and provision of care and services
2) Implementing governing body directives and organizational policies and procedures
3) Complying with applicable laws and regulations
4) Recruiting, employing, and retaining qualified personnel to maintain appropriate staffing levels
5) Ensuring adequate staff education
6) Completing performance evaluations on subordinate staff in accordance with organizational policy
7) Directing and monitoring organizational Performance Improvement activities
8) Managing operations in accordance with established fiscal parameters
9) Planning, developing, implementing, administering and evaluating programs
10) Representing the organization to other groups, organizations and the general public
11) Ensuring the accuracy of public information materials
12) Informing the governing body and staff of current organizational, community, and industry trends

LEGEND:

D - DOCUMENTATION
I - INTERVIEW
O - OBSERVATION
S - SURVEY

CI.5

I: Management and advisory/governing body members describe process for development, revision and annual review of policies. (CI.5a)

D: Administrative policies and procedures address the areas delineated in CI.5b.

D: A written safety program sets the parameters for monitoring environmental conditions and identifying potential hazards/risks in accordance with elements such as biomedical waste management, storage and handling of environmental cleaning supplies, fire safety, preventive maintenance of equipment, reporting of malfunctioning equipment, environmental controls to prevent client or staff accidents and or incidents and safety of clients and employees in the community. (CI.5b)

D: Operational policies and procedures detail planning, delivery and evaluation of care and include the 16 elements of CI.5c.

D: Personnel policies address the 9 elements of CI.5d.

Note: The Medicare Certified home health agency must comply with CFR 484.10(d), 484.11, 484.12(b-c), 484.14(e), 484.16, 484.18, 484.18(b-c), 484.48(a-b), 484.52, 484.52(b), 484.55. See Appendix I HH for a full text of the regulations and a cross-walk.

Note: The Medicare Certified hospice organization must comply with CFR 418.50(c), 418.74, 418.74(a,b). See Appendix IH for a full text of the regulations and a crosswalk.

CI.5	Organizational policies and procedures reflect an emphasis on quality and ethical practice and relate directly to the mission of the organization.

CI.5a Policies and procedures are developed, revised, and reviewed annually to assure currency of information.

CI.5b Administrative policies and procedures delineate administrative authority and responsibility for governance, planning, financial control and personnel. Policies include at a minimum:

1) Written Disclosure of conflict of interest
2) Public Disclosure of information
3) Responsibilities of ethical issues review group
4) Rights and responsibilities of clients
5) Internal and External Complaint Management
6) Exposure control plan
7) Formal safety program
8) Financial policies and procedures
9) Research activities/investigational studies as applicable.

CI.5c Operational policies and procedures form the framework for planning, delivery and evaluation of care and services provided. Policies include at a minimum:

1) Non-discrimination statement addressing admission of clients to service
2) Defined criteria for the acceptance or non acceptance of clients
3) Admission, continuation of service and discharge
4) Standardized assessment process
5) Referral to other providers of care or services
6) Medical orders, verbal orders and physician oversight as applicable
7) Emergency service
8) After hours service
9) Confidentiality of protected health information
10) Emergency/disaster preparedness
11) Health, safety and security of staff during all hours of work
12) Services/products provided directly and under contract
13) Standards of practice for all disciplines as applicable
14) Standards of operation for all products as applicable
15) Infection control
16) Accepted medical term abbreviations

CI.5d Personnel policies are developed and revised in response to organizational change and include:

1) Conditions of employment
2) Respective obligations between employer and employee
3) Non-discrimination information
4) Grievance procedures
5) Employee orientation
6) Employee exit interviews
7) Maintenance of health reports and protected employee information
8) Employee record confidentiality and record retention
9) Recruitment, retention and performance evaluation of staff

LEGEND:

D - DOCUMENTATION
I - INTERVIEW
O - OBSERVATION
S - SURVEY

CI.5 (Continued)

D: Written TB Exposure Control Plan includes the elements in CI.5e.

D: Written policy and procedure define the requirements of Medical Device Act reporting. (CI.5f)

D: Medical Device Act reports, as applicable, are on file in the organization and include validation of submission to the FDA which may include an incident that results in death and when the manufacturer is unknown. (CI.5f)

D: Written infection control policies and procedures include the elements in CI.5g.

CI.5e The organization's written TB Exposure Control Plan is in compliance with the most current Centers for Disease Control & Prevention (CDC) applicable recommendations and requirements for occupational exposure to Tuberculosis. The plan addresses:

1) Definition of employees at risk of occupational exposure to TB
2) Process for identifying suspected or confirmed cases of TB
3) Control of employee exposure when a patient is suspected/confirmed as having infectious TB
4) Provision of education and training to all employees to the hazards of exposure to TB at the time of employment and annually thereafter
5) Pre-employment and subsequent periodic TB screening of employees in accordance with written policy
6) Provision of follow up care to employees exposed to TB
7) Provision of follow up care to employees who convert to active disease
8) Provision of appropriate personal protective equipment when caring for a suspected/confirmed TB client
9) Provision of work practice oversight to minimize occupational exposure to TB
10) Adherence to reporting and record keeping requirements per state and federal law

CI.5f Organizational policy and procedure address the requirements of the Medical Device Act (MDA) and delineate the mechanisms for reporting incidents, which result in serious injury, illness or death.

1) Reports are filed with the Federal Drug Administration according to regulation
2) A designated person is responsible for ensuring compliance with reporting requirements
3) Criteria for designation of reportable events are clearly defined
4) Written protocols for the investigation of events are clearly defined
5) Investigative activities are initiated on a timely basis
6) Accurate documentation of findings include:
   (a) Investigative findings
   (b) Copies of reports sent to the manufacturer
   (c) Copies of reports to FDA
7) Retention and retrieval of findings and reports
8) In-service education on Medical Device Act reporting is provided to staff on an annual basis
   (a) Written curriculum outlines describe training content
   (b) Records of attendance are maintained

CI.5g Infection Control policies and procedures detail systems designed to promote the prevention and control of infections, monitor the occurrence of infections and evaluate the effectiveness of infection control practices.

1) Current infection control practices and strategies
2) Identification and investigation of breaks in technique
3) Sources of infection:
   (a) Nosocomial
   (b) Home acquired
   (c) Professional exposure
4) Types of infection
5) Modes of transmission of infection

LEGEND:

D - DOCUMENTATION
I - INTERVIEW
O - OBSERVATION
S - SURVEY

CI.5 (Continued)

D: Written policy and procedure define the parameters for ensuring the safety, security, and confidentiality of clinical hardcopy, automated, and/or travel records. (CI.5h).

D: Written policies and procedures define the parameters that ensure the client's right to access client record information and to release client record information. (CI.5h)

D: Written policy and procedure and local/state /federal regulations dictate the secure retention of all types of clinical records. (CI.5h)

D: Written policy and procedure details the process for release of information. (CI.5h)

I: Records administrator or other designated party describes adherence to policy and procedure. (CI.5h)

I: Staff describe process for accessing policies and procedures. (CI.5i)

6) Contributing causes of infection
7) Data collection, analysis, and tracking and trending of findings
8) Reporting requirements per state and federal regulations
9) In-service education for staff
   (a) Dates and times of programs
   (b) Curriculum outline of training content
   (c) Records of staff attendance
10) Client and/or family teaching
11) Use of personal protective equipment
12) Accepted hand hygiene techniques

CI.5h Administrative, financial, client and personnel records are secured, retained and retrievable in accordance with a formal record retention policy that is in compliance with organizational policy and local, state and federal law.

1) Minutes of all official meetings of the governing body are retained for a minimum of five (5) years.
2) Client adult records are retained for a minimum of five (5) years after provision of service.
3) Client records of minors are retained for a minimum of seven (7) years after the age of majority is reached.
4) Mechanisms for client access and release of client records are defined.
5) Authorization for client record documentation and entry and signature authorization and authentication for automated client record system in accordance with individual state law are defined.
6) Process for maintaining safety and security of client records is defined.
7) Confidential records for employees experiencing an occupational exposure are retained for the duration of employment plus thirty (30) years.
8) Annual training records for exposure prone employees are retained for a minimum of three (3) years.
9) Client records involved in litigation are retained until after settlement.

CI.5i Staff members have access to policies and procedures.

LEGEND:

D - DOCUMENTATION
I - INTERVIEW
O - OBSERVATION
S - SURVEY

CI.6

D: Informational materials, written in different languages are available and provided to clients/families as appropriate. (CI.6a)

I: Administrative/management personnel articulate cultural diversity in the community population and describe the organization's ability to meet special needs. (CI.6a)

I: Staff members demonstrate awareness and use of available resource materials, and clients/families verbalize knowledge of pertinent resources. (CI.6a)

I: Clients/families of different cultures acknowledge receipt of language specific materials and care provided by bi-lingual staff, family members and/or the use of interpreters as appropriate and necessary. (CI.6b)

Note: The Medicare Certified home health agency must comply with CFR 484.12(a). See Appendix I HH for a full text of the regulations and a cross-walk.

CI.6	Information is provided to clients/families identifying availability of organizational and community resources to assist in meeting client needs

CI.6a Language specific written materials, as necessary and appropriate, are available for distribution to client/families.

CI.6b Interpretive services are provided, as indicated and necessary, to ensure accurate communication between the client/family/caregiver and other types of health services personnel.

LEGEND:

D - DOCUMENTATION
I - INTERVIEW
O - OBSERVATION
S - SURVEY

CI.7

D:	Written policy delineates the make up and function of the designated group to review ethical issues. Authority may be self-vested in the governing body, in an independent entity or in an advisory group. (CI.7a, b)
I:	Administrative/management/staff personnel describe the structure of the ethical group and the process for handling ethical concerns and issues. (CI.7b)
D:	Meeting minutes document discussions of and actions taken by the group, as applicable. (CI.7c)

CI.7	The organization's business, clinical, disease prevention and health promotion activities are conducted according to ethical standards.

CI.7a A group of qualified professionals is designated by the governing body to review ethical issues as they arise.

CI.7b Organizational policy and procedure outlines the responsibilities of the group and delineates the process for submitting ethical concerns and issues for action.

CI.7c Meeting minutes clearly document group activities and are referred to the governing body for review and final action as indicated and necessary.

LEGEND:

D - DOCUMENTATION
I - INTERVIEW
O - OBSERVATION
S - SURVEY

CI.8

I:	Administrative/management personnel describe that careful consideration is given to providing a site for relevant research, that human subjects involved in any part of research activities provide written informed consent, and that specific parameters for protection of participants and confidentiality of personal information are clearly defined. (CI.8a)
D:	Policy and procedure establish the parameters for research initiatives as applicable. (CI.8b)
D:	Current research activities as applicable ensure compliance with CI.8a,b, c, d.
I:	Administrative/management personnel describe current research initiatives as applicable. (CI.8c)
I:	Staff describes use of research knowledge which was integrated into practice as applicable. (CI.8e)

CI.8	The organization considers requests for research in the area of community/public health as appropriate.

CI.8a A mechanism is in place for reviewing, processing, and approving internal and external research proposals.

CI.8b Organizational policy and procedure defines parameters for participation in research activities and investigative studies.

1) Research protocols, as applicable, for internally and externally sponsored activities are on file
2) Potential participants are provided with written information regarding the nature, process, and benefits of the research outcomes
3) Risks associated with the project are clearly delineated

CI.8c Organizations participating in research or investigative studies ensure that clients and staff are fully informed.

CI.8d Formal written consents for participants in research and/or investigative studies are obtained and retained on file in the organization.

CI.8e New knowledge from internal and external research is integrated into practice as applicable.

CII.
THE ORGANIZATION CONSISTENTLY PROVIDES HIGH QUALITY SERVICES AND PRODUCTS

LEGEND:

D - DOCUMENTATION
I - INTERVIEW
O - OBSERVATION
S - SURVEY

CII.1

D: **Current Public Disclosure Policy addresses applicable elements of CII.1a.**

D: **The Client Bill of Rights includes the elements of CII.1b.**

I: **Clients confirm the timely receipt of the Client Bill of Rights and other admission information. (CII.1c)**

Note: Advising clients of their rights is not applicable under conditions of emergency/disaster intervention and mass clinics.

D: **Documented evidence in the client records confirms receipt of the Client Bill of Rights and other admission information. (CII.1d)**

Note: Advising clients of their rights is not applicable under conditions of emergency/disaster intervention and mass clinics.

I: **Clients/families articulate understanding of the information provided and describe how they have found the information to be helpful. (CII.1d)**

Note: The Medicare Certified home health agency must comply with CFR 484.10, 484.10(a-e), 484.12. See Appendix I HH for a full text of the regulations and a cross-walk.

Note: The Medicare Certified hospice organization must comply with CFR 418.50(c). See Appendix IH for a full text of the regulations and a crosswalk.

CII.1 The mission drives the activities of the organization and ensures public disclosure, client rights and ethical standards of business and clinical practice.

CII.1a A public disclosure policy defines the availability and accessibility of public information which includes ownership information, statement of the organization's mission, and licensure and accreditation status, as applicable.

CII.1b A written Client Bill of Rights is designed to recognize, protect, and promote the right of each client to be treated with dignity and respect.

1) Written policy and procedure defines the rights and responsibilities of clients.
2) Notice of rights is provided to clients in advance of providing pre-planned care.
3) The client is knowledgeable of the right to exercise his/her rights at any time.
4) The organization maintains documentation of compliance of distribution of required information to clients.
5) The client/client's designated representative is authorized to exercise their rights.
6) Confidentiality of the client record/data is maintained by the organization.
7) Access to care/service is based upon non-discrimination.
8) Clients are informed that they have the right to voice complaints/grievances to the organization regarding treatment/care/service without fear of discrimination or reprisal for doing so.
9) The organization provides the client the telephone number for the CHAP hot line, including the hours of operation and the purpose of the hotline to receive complaints or questions about the organization.
10) Clients are informed that they have the right to participate in the development of care and service plans.
11) Clients are informed verbally and in writing of billing and reimbursement methodologies prior to start of care and as changes occur, including fees for services/products provided, direct pay responsibilities, and notification of insurance coverage.

CII.1c Written admission documents, provided to the client or the client's representative prior to or at the time of initiation of care/service, ensure organizational compliance with the Client Bill of Rights and other regulatory requirements.

CII.1d A reasonable attempt is made and documented to ensure that the client and family understand their rights and responsibilities which are reviewed with the client prior to or at the time of initiation of care and periodically thereafter.

LEGEND:

D - DOCUMENTATION
I - INTERVIEW
O - OBSERVATION
S - SURVEY

CII.2

I:	Clients/families describe methods used to contact the organization during regular hours of service, after hours, weekends and holidays. (CII.2a)
I:	Professional, technical, and support staff describe coordination and collaboration between disciplines. (CII.2b)
I:	Professional, technical, and support staff describe coordination and collaboration with sub-contract and/or independent contractor providers of care. (CII.2b)
I:	Clinical supervisors and staff describe the on-call system for services after normal organization hours. (CII.2c)
O:	Testing the after hours on call system validates compliance with organizational policy and procedure. (CII.2c)

CII.2	Care, services, and products are available to and accessible by the client/client representative.

CII.2a Care, services, and products are provided within an established time frame, as specified by organizational policy, organizational standards, medical directives or individual physician orders. Consideration is given to client and/or family needs in scheduling and providing care.

CII.2b Collaboration and networking with other providers enhance provision of care and services as applicable.

CII.2c Supervisory and clinical/service staff demonstrate knowledge of organizational policy and procedure for ensuring delivery of care, services and products to clients.

LEGEND:

D - DOCUMENTATION
I - INTERVIEW
O - OBSERVATION
S - SURVEY

CII.3

D:	Written information distributed to clients/families address disasters/emergencies as applicable to the organization's service area. (CII.3a)
I:	Clients/families are aware of their responsibilities in the event of an emergency episode. (CII.3a)
D:	Staff are oriented to written protocols that ensure the safety and security of personnel. (CII.3b)
D:	Disaster drills are documented as applicable to the organization. (CII.3c)
I:	Administrative/management staff describe roles and responsibilities of personnel during an emergency episode. (CII.3c)
I:	Staff members at all levels demonstrate awareness of responsibilities to ensure the safety of self and others. (CII.3c)

Note: The Medicare Certified hospice organization must comply with CFR 418.100. See Appendix IH for a full text of the regulations and a crosswalk.

CII.3	A geographic specific plan defines the protocols for prioritizing the delivery of care and services to clients and protects the safety of staff during disasters, emergencies and/or environmentally challenging situations.

CII.3a Detailed written instructions are given to clients and/or family members to ensure an appropriate and timely response on the part of the client and/or family in the event of a natural disaster, inclement weather, and/or other emergent event that might cause an interruption in the provision of services.

CII.3b Written protocols define management responsibilities in ensuring the safety and security of staff prior to or during an emergent event.

CII.3c Staff are knowledgeable of the practices and procedures relating to emergency preparedness responsibilities and emergent events.

LEGEND:

D - DOCUMENTATION
I - INTERVIEW
O - OBSERVATION
S - SURVEY

CII.4

D: Client records document coordination of care activities. including planning, implementation, monitoring and evaluation of care/service as appropriate. (CII.4)

I: Clinical/service, financial, and operational staff describes collaboration and support among all disciplines and organizational divisions. (CII.4a)

O: Organizational planning meetings as available and appropriate. (CII.4a)

Note: The Medicare Certified home health agency must comply with CFR 484.14(g). See Appendix I HH for a full text of the regulations and a cross-walk.

CII.4	Inter and intra organizational coordination is evident in the planning, implementation, monitoring, and evaluation of care and services provided.

CII.4a Coordination between the clinical/service, financial, and operational components of the organization is evident.

LEGEND:

D - DOCUMENTATION
I - INTERVIEW
O - OBSERVATION
S - SURVEY

CII.5

I: Professional, technical, and support staff describe protocols that protect client/family information regarding confidentiality of information, use of travel record and transport and storage of travel record. (CII.5a).

I: Office staff describe ongoing security of client record information. (CII.5a)

I: Staff is knowledgeable of the client's right for access to and release of client information. (CII.5a)

O: Active and inactive client records are maintained in a secure area during working and non-working hours that is inaccessible to unauthorized individuals. (CII.5a)

S: Random sample of client records reviewed provides evidence of compliance with organizational policy, standards and regulatory requirements. (CII.5c,d)

O: Automated client record systems include safeguards. (CII.5e)

I: Client records administrator describes process for ensuring consistent, ongoing validation and protection of automated records data including prevention of lost data due to equipment failure and storage of backed-up files. (CII.5e)

I: Evidence is provided validating periodic review and updating of the record format used. (CII.5f)

I & O: Managers/staff describe and demonstrate compliance with policy and procedure governing the coordination, transport, and security of information shared with and between alternate sites. Staff describe the type of information that is maintained and the procedures for coordination, communication, exchange, and retrieval of required information with the parent organization. (CII.5g)

Note: The Medicare Certified home health agency must comply with CFR 484.10, 484.11, 484.14, 484.18(c), 484.48, 484.48(b), 484.52(b).. See Appendix I HH for a full text of the regulations and a cross-walk.

Note: The Medicare Certified hospice organization must comply with CFR 418.74, 418.74(a,b). See Appendix IH for a full text of the regulations and a crosswalk.

CII.5	Client records, maintained for each client or client group, are utilized as a tool for coordination of services, as a legal document that is descriptive of care and services provided, and as a resource document for billing and reimbursement.

CII.5a All protected health information or client records, hardcopy or automated, are kept confidential and are safeguarded against loss or unauthorized use in accordance with organizational policy and local, state or federal regulations.

CII.5b Clients have access to their records and are informed of the process.

CII.5c The client record documentation provides client information specific to care and services/products provided, current client status, and progress toward goals and outcomes of care.

CII.5d Entries to client record documentation is made only by authorized staff and in accordance with organizational policy and procedure.

CII.5e Automated client record systems ensure consistent and ongoing security and protection of data.

CII.5f The format for maintenance of client records is reviewed and updated as necessary.

CII.5g Organizations with alternate sites ensure consistent documentation, communication, coordination, and retrieval of significant administrative and client/family information.

LEGEND:

D - DOCUMENTATION
I - INTERVIEW
O - OBSERVATION
S - SURVEY

CII.6

D: Data reflect measurement of quality of services outcomes. (CII.6a)

I: Performance improvement manager describes rationale for the performance improvement process and the definition of specific client/service outcomes. (CII.6b,d,e)

D: A structured framework exists. (CII.6c)

D: A client satisfaction survey for the current year is available for review and includes, at a minimum, client satisfaction with care and services provided and satisfaction with providers of care. (CII.6f)

I: The organization describes the mechanism for monitoring client satisfaction. (CII.6f)

D: Evidence exists of utilization of performance improvement findings to resolve problems and improve quality of service/ products. (CII.6g)

D: Organizational committees and governing body minutes document reporting of trends of performance improvement findings. (CII.6h)

Note: The Medicare Certified home health agency must comply with CFR 484.52, 484.52(a). See Appendix I HH for a full text of the regulations and a cross-walk.

Note: The Medicare Certified hospice organization must comply with CFR 418.66, 418.66(a, b, c). See Appendix IH for a full text of the regulations and a crosswalk.

CII.6	A comprehensive Performance Improvement process integrates the organization's mission and promotes an organizational wide approach that selects, reviews, and analyzes outcomes specific to organizational needs and the scope of services and products.

CII.6a Quality is defined and measured in terms of client/service outcomes.

CII.6b Specific outcomes are targeted for improvement or replication.

CII.6c The organization develops a structured framework for the investigation of target outcomes.

CII.6d The organization identifies outcomes to benchmark by utilizing internal standards, processes and protocols; practice or service guidelines; industry research and/or best practices.

CII.6e The organization continually evaluates progress toward outcomes and identifies new areas to improve or replicate as indicated by results of data analysis.

CII.6f A process for monitoring and measuring the satisfaction levels of clients is conducted at least annually.

CII.6g Performance Improvement findings are used to resolve identified problems, improve quality of services and products, and are incorporated into program planning, modification and /or enhancement.

CII.6h Trends of Performance Improvement findings are reported to appropriate organizational committees and the governing body.

LEGEND:

D - DOCUMENTATION
I - INTERVIEW
O - OBSERVATION
S - SURVEY
CII.7

D: Personnel records include evidence of adherence to regulatory requirements of Federal OSHA and CDC. (CII.7a)

D: Written plans define parameters for exposure control, adherence to standard precautions, adherence to work practice controls, HBV prophylaxis and TB exposure control. (CII.7b)

D: Potential for employee exposure is determined by job classification, which defines the potential for risk and includes: (CII.7c)
a) Definition of types of tasks and/or procedures that place an employee at risk for exposure.
b) Description of job classifications in which all employees have the potential for occupational exposure.
c) Description of job classifications in which employees have the potential for occasional exposure.
d) Description of job classifications in which employees have no risk for occupationally related exposure.

O: Staff demonstrate adherence to standard precautions as determined by organizational policy: (CII.7d)
a) Use of gloves
b) Use of and accessibility to masks and protective eyewear
c) Use of protective gowns and aprons
d) Hand hygiene/hand washing techniques including the use of chemical substances
e) Techniques for minimizing needle sticks
f) Use of puncture resistant sharps containers
g) Proper transportation and storage of sharps
h) Disposal of contaminated supplies and equipment on site

S: Random sample of employee records provides evidence of compliance with Hepatitis B (HBV) prophylaxis program. (CII.7f)

I: Designated person describes procedures followed to ensure compliance with investigative requirements and protection of the rights of the employee who has experienced an occupational exposure. (CII.7f)

D: Education and training records document compliance with training requirements. (CII.7g)

Note: The Medicare Certified home health agency must comply with CFR 484.12(c). See Appendix I HH for a full text of the regulations and a cross-walk.

Note: The Medicare Certified hospice organization must comply with CFR 418.50(b), 418.100 (c), 418.100(i). See Appendix IH for a full text of the regulations and a crosswalk.

CII.7	The health and safety of employees and clients is promoted and enhanced through education, current application of infection control practices and implementation of appropriate safety measures.

CII.7a Adherence to State and/or Federal Occupational Health and Safety Administration (OSHA) and Centers for Disease Control & Prevention (CDC) requirements as applicable that address the health and safety of employees and clients and their protection from blood borne pathogens are validated.

CII.7b The organization implements its written Exposure Control Plan.

CII.7c The potential for occupational exposure is determined for all job classifications in accordance with state, federal and Occupational Health and Safety Administration (OSHA) mandate.

CII.7d Adherence to the use of Standard Precautions by job classification is documented.

CII.7e Adherence to work practice and engineering controls is evident in practice.

1) Physical work sites are maintained in a clean and sanitary condition
2) Use of disinfectant solutions
3) Handling, transporting, storage and processing of soiled/contaminated materials, supplies and equipment
4) Use of non-leak infectious waste containers as applicable
5) Identification and labeling of infectious waste as applicable

CII.7f Employer and employee responsibilities relating to Hepatitis B prophylaxis (HBV) are defined in writing and include:

1) HBV vaccination and post exposure follow up program
2) Employer/employee responsibilities
3) Declination of HBV statement is signed by employees as applicable and filed in personnel health records
4) Complete and detailed documentation of all exposure events
5) Confidential records are maintained on HBV vaccination and post exposure follow up

CII.7g Education and training programs ensure that new employee orientation addresses all aspects of the Exposure Control Plan and that annual training is mandated for all exposure prone employees based on applicable job classification.

LEGEND:

D - DOCUMENTATION
I - INTERVIEW
O - OBSERVATION
S - SURVEY

CII.7 (Continued)

D: Occupational exposure information is maintained in confidential records that are retained for the duration of employment plus thirty (30) years. (CII.7h)

I & O: Clinical, technical and support staff describe potential hazards in the home setting identified during the assessment of the client's living environment. (CII.7k)

D & I: Evidence exists that the organization monitors and reports information related to adverse events.
Adverse events include but are not limited to:

- provision of care errors
- unusual occurrences
- vehicular crashes
- other types of accidents or injury
- safety hazards

Serious Adverse Events include but are not limited to:

- unexpected death not resulting from the client's medical condition
- loss of body part
- permanent or partial loss of body function
- blindness

Reports document data on adverse events that predispose the organization to real or potential liability.

- Data are collected within 30 days of an event
- Data are analyzed within 60 days of the event to determine underlying factors leading to the adverse event
- Performance Improvement processes, as applicable, include evidence of organizational changes subsequent to an adverse event

(CII.7l)

D: Medical Device Act reports, as applicable, are on file in the organization and include validation of submission to the FDA. (CII.7m)

I & O: Staff demonstrate knowledge of and compliance with the organizational infection control practices and procedures . (CII.7n)

CII.7h The organization demonstrates compliance with its Occupational Exposure Control policies, plan and procedures.

1) HBV is provided at no cost to all employees, potentially subject to occupational exposure, within ten (10) working days of assignments
2) Provision of personal protective equipment as appropriate to all employees with the potential for an occupational exposure as determined by their job classification
3) A confidential medical evaluation and follow-up care is offered to employees who experience an occupational exposure:
   (a) Counseling
   (b) Testing of source individual if allowable under local and/or state law
   (c) Blood testing of the exposed employee with written consent, if medically indicated
4) Accurate, confidential, and timely documentation of:
   (a) Circumstances leading to exposure
   (b) Routes of exposure
   (c) Medical follow-up
   (d) Opportunity for counseling
   (e) Other related interventions as indicated and necessary

CII.7i The organization demonstrates compliance with its TB Exposure Control Plan.

CII.7j The organization demonstrates compliance with its safety program to monitor environmental conditions for identifying potential hazards/risks.

CII.7k A routine assessment is made of the client's living environment to identify and evaluate potential safety hazards related to the physical space as applicable.

CII.7l A system is in place for monitoring and reporting information related to adverse events that endanger the health and safety of clients and/or employees and pre-dispose the organization to real or potential liability.

1) Adverse Events and Serious Adverse Events are defined in organizational policy
2) Data for all events is collected, analyzed tracked and trended as a part of risk management
3) Corrective actions are implemented and evaluated as indicated and necessary
4) Adverse event reports detail each episode and are distributed to advisory boards and accrediting bodies, as applicable

CII.7m The organization demonstrates compliance with its policy and procedure for the Medical Device Act (MDA).

CII.7n The organization demonstrates compliance with its Infection Control policies and procedures.

LEGEND:

D - DOCUMENTATION
I - INTERVIEW
O - OBSERVATION
S - SURVEY

CII.8

D: Examples of complaint documentation logs. (CII.8a)

D: Formal documentation of investigative findings and reports as applicable. (CII.8a)

D: Resolution information is documented as communicated to the complainant. The communication to complainant may be in writing or by telephone. (CII.8b)

I: Staff describes an understanding of the complaint process. (CII.8c)

Note: The Medicare Certified home health agency must comply with CFR 484.10(b). See Appendix I HH for a full text of the regulations and a cross-walk.

CI1.8	Client/ family complaints/concerns are responded to and resolved in a timely manner.

CII.8a The complaint process includes intake, investigation, and corrective action as applicable, complaint resolution, written reports, organizational trending and follow-up.

CII.8b Resolution/outcome information is communicated to the complainant.

CII.8c Staff are aware of organizational mechanisms for receiving and resolving complaints.

CIII.
THE ORGANIZATION HAS ADEQUATE HUMAN, FINANCIAL AND PHYSICAL RESOURCES WHICH ARE EFFECTIVELY ORGANIZED TO ACCOMPLISH ITS STATED MISSION/PURPOSE

LEGEND:

D - DOCUMENTATION
I - INTERVIEW
O - OBSERVATION
S - SURVEY

CIII.1

D: Policy, procedure and recruitment documents support a non-discriminatory approach to hiring. (CIII.1a)

I&O: Interviews with staff and observation of client practice/service validate adherence to discipline specific practice standards and to regulatory guidelines and requirements specific to respective areas of responsibility. (CIII.1b)

I: Staff confirm clear understanding of responsibilities and lines of authority. (CIII.1c)

I: Management explains turnover rate variances as applicable, and describes impact on recruitment and retention activities. (CIII.1d)

D: Employee records validate the opportunity for a formal exit interview for terminating employees in accordance with organizational policy and procedure. (CIII.1e)

I: Employees validate receipt of conditions of employment and describe the process for obtaining personnel related information. (CIII.1f)

D: Employee files are complete and current and include documents specific to CIII.1g. Evidence of verification of education/training may include copies of diplomas, transcripts or telephone validation.

O: Specified personnel documents are secured in accordance with organizational policy. (CIII.1h)

Note: The Medicare Certified home health agency must comply with CFR 484.12(c), 484.14(c,e), 484.30(a), 484.32, 484.32(a), 484.34, 484.36(b). See Appendix I HH for a full text of the regulations and a cross-walk.

Note: The Medicare Certified hospice organization must comply with CFR 418.64, 418.70(a,b). See Appendix IH for a full text of the regulations and a crosswalk.

CIII.1	The organization has adequate and appropriate human resources to meet caseload and workload demands.

CIII.1a A non-discriminatory recruitment and selection process, as defined in policy and procedure, is adhered to.

CIII.1b Personnel are employed and assigned responsibilities commensurate with their education and experience.

CIII.1c Job Descriptions for each employee category delineate lines of authority and reporting responsibilities, duties to be performed, and educational and experiential qualifications specific to the position.

CIII.1d Employee turnover rates are monitored tracked and trended, as applicable.

CIII.1e The opportunity for exit conferences are offered to terminating employees, are documented and trended, as applicable.

CIII.1f Personnel policies/conditions of employment are provided to employees at the time of hire and thereafter as updates/revisions are needed.

CIII.1g Evidence of the following employee information is maintained in accordance with organizational policy and regulatory guidelines.

1) Individual job qualifications
2) Verification of education/training
3) Certification for specialty areas of practice as applicable
4) Statement of formal training for non-professionals
5) Two (2) reference checks
6) Pre-employment interview(s)
7) Current license or certification as applicable
8) Validation of competency skills testing as applicable
   (a) Time of hire
   (b) Annual
9) Validation of performance evaluation at end of probation and annually
10) Validation of malpractice coverage for independent contractors
11) Validation of completion of the orientation process (new and reassigned personnel)
12) Validation of signed and dated confidentiality statements
13) Validation of in-service/continuing education participation as applicable
14) Validation of exit interview as applicable
15) Miscellaneous items per state, federal or organizational requirements
16) Criminal background checks in accordance with organizational policy and procedure and local and/or state law
17) Immigration and naturalization statement (I-9)

CIII.1h Specified personnel documents and employee health reports may be retained in separate files per organization policy.

LEGEND:

D - DOCUMENTATION
I - INTERVIEW
O - OBSERVATION
S - SURVEY

CIII.1 (Continued)

D: Annual evaluation form addresses elements of CIII.1i as applicable to the job category.

I: Sample of employee and supervisory staff personnel records confirms adherence to the annual evaluation process. (CIII.1i, 1j)

D: A written plan details the orientation of new personnel and for personnel assigned to a new job classification. Components of the orientation plan may include mission and purpose of the organization, table of organization, lines of authority and responsibility, hours of work, job-related responsibilities, and personnel policies. (CIII.1k)

I: Recent hires describe their orientation as comprehensive and pertinent to meeting job responsibilities. (CIII.1k)

I: Staff assigned to a new job classification describe their orientation to the new responsibilities. (CIII.1k)

I: Staff validate receiving applicable hours of in-service programming and describe the types of experiences available to them. (CIII.1l)

O: Federally required in-services include OSHA mandated. Staff Development opportunities may include: independent study, satellite learning, specialized conferences, formal courses of study and mentoring. (CIII.1l)

D & I: Policy and managers describe the process for assuring that personnel are identified. Service contracts with organizations detail the process that the sub-contract organization will assure sub-contract organization identification of staff. (CIII.1m)

CIII.1i An annual written performance evaluation process is completed on all employees by the respective supervisor and includes:

1) Supervisor assessment of employee performance in accordance with established criteria (Job Description)
2) Achievement of previously established goals
3) On site evaluation reports/competency testing for clinical/field/service staff
4) A signed, dated validation of the evaluation process by the employee and employer representative

CIII.1j An annual performance evaluation process provides an opportunity for active participation by employees through:

1) Employee development planning/new goal setting
2) Employee response to evaluation

CIII.1k A written plan details the orientation process for all new and reassigned employees which addresses applicable elements pertinent to each job classification.

CIII.1l The organization shall provide in-service and staff development as needed and as required by local, state and federal regulation and national and/or professional standards as applicable.

CIII.1m Personnel are provided with identification badges or are identified as working for the organization.

LEGEND:

D - DOCUMENTATION
I - INTERVIEW
O - OBSERVATION
S - SURVEY

CIII.2

D: **A review of a randomized sample of written contracts for the provision of care, services and/or products validates adherence to CIII.2, a, b.**

I: **Contract manager or other designated party describes the ongoing management and control of contractual agreements. (CIII.2a)**

Note: The Medicare Certified home health agency must comply with CFR 484.14, 484.14(f, h), 484.36(d). See Appendix I HH for a full text of the regulations and a cross-walk.

Note: The Medicare Certified hospice organization must comply with CFR 418.56, 418.56(b,c,d,e), 418.80). See Appendix IH for a full text of the regulations and a crosswalk.

CIII.2	Formal written contracts, executed by the primary organization with other professionals and entities for the provision of care, services, and products to clients of the primary organization, detail specific responsibilities of the parties involved.

CIII.2a Written service contracts with individuals and/or other entities are signed and dated by authorized principals of each party and are reviewed annually.

CIII.2b The executed document stipulates the terms of the contract which include:

1) Specific services/products to be provided
2) Contractor is required to adhere to applicable primary organization's policies and procedures
3) Assurance by the contractor of the education, training, qualifications and identification of personnel designated to provide care, services, and products
4) Mechanisms for the contractor parties to participate in Performance Improvement activities as applicable
5) Procedures for the documentation and submission of documented notes that verify the provision of services/products in accordance with the written service contract
6) Procedures for the submission of bills and related information and reimbursement for care, services and products provided
7) Effective dates of the contract including terms of renewal and/or termination

LEGEND:

D - DOCUMENTATION
I - INTERVIEW
O - OBSERVATION
S - SURVEY

CIII.3

D: Organizational policy and procedure detail the fiscal activities and responsibilities of the organization. (CIII.3a)

I: The chief financial manager confirms credentials and experience background for the responsibilities assigned and describes the budget planning process. (CIII.3b)

D: Governing Body minutes confirm approval of budgets and other financial agenda items referred to the Governing Body. (CIII.3c)

D: The organization has a current operating budget and capital expenditure plan. (CIII.3d)

D: Financial, statistical and productivity reports are used to facilitate oversight of the organization's operations. (CIII.3e)

I: The chief financial manager describes the use of financial, statistical or productivity reports. (CIII.3e)

I: The chief financial manager validates the adequacy of insurance coverage. (CIII.3f)

D: Review of annual financial review validates that the review was conducted by an organization external to the organization within the most recent twelve month period. (CIII.3g)

Note: The Medicare Certified home health agency must comply with CFR 484.14(i). See Appendix I HH for a full text of the regulations and a cross-walk.

Note: The Medicare Certified hospice organization must comply with CFR 418.52, 418.56(d). See Appendix IH for a full text of the regulations and a crosswalk.

CIII.3 The organization's sources of financial support are managed and monitored on an ongoing basis to ensure the availability of adequate funding.

CIII.3a Financial policies and procedures govern the fiscal activities of the organization.

CIII.3b The chief financial manager has the appropriate qualifications, credentials and expertise to oversee, manage, and direct the fiscal operations of the organization.

CIII.3c Major participants in developing and monitoring the budgetary process include the governing body, the chief executive, the chief financial manager, program directors and other designated staff as appropriate.

CIII.3d The operating budget and operating capital expenditure plan is developed using methodologies commensurate with the scope and complexity of the organization's services, programs, and products and is used to forecast financial and operating successes and challenges.

CIII.3e Financial management tools are used to provide operational feedback to administrative and management personnel, financial committees and the governing body.

CIII.3f Adequate insurance coverage is maintained.

CIII.3g An annual external review is required and conducted.

LEGEND:

D - DOCUMENTATION
I - INTERVIEW
O - OBSERVATION
S - SURVEY

CIII.4

D: Financial reports detail information used to measure operational performance. (CIII.4a, b)

I: The chief financial manager or other designated party describes the effectiveness of the financial management information systems, the types of reports generated and their use, and internal financial controls (CIII.4a, b, c)

D: Organizational financial procedures used for internal control may include segregation of duties, reconciliation of control accounts, approval levels for disbursements and adjustments, collection of accounts receivable, budgeting, receipt of funds, disbursement of funds, cash and asset account reconciliation and cash management. (CIII.4c)

I: Financial /billing staff confirms timely billing procedures, ongoing monitoring of accounts receivable, implementation of collection efforts as appropriate, and adherence to accounts receivable guidelines. (CIII.4d)

D: Financial reports include payroll and vendor disbursements in accordance with CIII.4e.

Note: The Medicare Certified home health agency must comply with CFR 484.14(i). See Appendix I HH for a full text of the regulations and a cross-walk.

CIII.4 A financial management information system is used to document and monitor all financial components and provide appropriate and timely reports to all levels within the organization.

CIII.4a The financial reporting system produces detailed data regarding actual transactions specific to care, services and products provided by each program including site/ location activity.

CIII.4b Periodic financial statements contain key indicators and show a reasonable match between revenue and expense line items.

CIII.4c Internal financial controls are in effect.

1) Internal audit procedures and annual review of budget are conducted.
2) Adherence to organizational financial policies and procedures is monitored.

CIII.4d Reimbursable services are billed on a timely basis in accordance with designated fee structures and are monitored, tracked and aged.

CIII.4e Payroll and vendor disbursements are recorded and processed in a structured and timely manner.

LEGEND:

D - DOCUMENTATION
I - INTERVIEW
O - OBSERVATION
S - SURVEY

CIII.5

D: Applicable statements indicating compliance with OSHA, CDC, ADA, are available and may include:

1) Fire drill and health inspection reports indicate compliance.
2) Certificates of occupancy are posted in accordance with local requirements.
3) Fire and emergency exits clearly detail areas of entrance and egress.
4) Hazardous area access is controlled.
5) Hazardous chemicals and solutions are properly labeled and kept in locked storage.
6) Adequate space and privacy is provided to employees and clients receiving services.
7) Facilities are barrier free and/or special arrangements are made to provide access as indicated and necessary.
8) Safety and security procedures for employees are implemented as necessary.

(CIII.5a)

O: Tour of facility validates compliance with OSHA, CDC, and ADA guidelines and applicable local requirements. (CIII.5a)

Note: The Medicare Certified home health agency must comply with CFR 484.12(a). See Appendix I HH for a full text of the regulations and a cross-walk.

Note: The Medicare Certified hospice organization must comply with CFR 418.56(c), 418.100(c). See Appendix IH for a full text of the regulations and a crosswalk.

CIII.5	Physical facilities are adequate to support the operations.

CIII.5a Physical facilities meet the OSHA (Federal/State), CDC, ADA and/or State or Local regulations for environmental protection and safety of employees and recipients of service.

LEGEND:

D - DOCUMENTATION
I - INTERVIEW
O - OBSERVATION
S - SURVEY

CIII.6

D&I: MIS manager or other designated party explains and demonstrates how data are collected, processed and secured on and off site. (CIII.6a)

I: Management describe how information system is used to ensure organizational accountability. (CIII.6)

CIII.6 A management information system is utilized to ensure accountability at all levels of the organization.

CIII.6a A manual or automated system utilizes established standards and defined data elements for the collection and processing of information.

CIV.

THE ORGANIZATION IS POSITIONED FOR LONG TERM VIABILITY

LEGEND:

D - DOCUMENTATION
I - INTERVIEW
O - OBSERVATION
S - SURVEY

CIV.1

I: Management and staff describe the planning process. (CIV.1a)

I&O&D: The assessment of the strengths, weaknesses, opportunities and threats may include the following components:

1) Assess and analyze service area demographics.
2) Maintain current knowledge of organization's market penetration.
3) Identify new and/or changing consumer and community needs.
4) Collect data and information for analysis.
5) Garner input from all levels of staff.
6) Determine organizational priorities.

(CIV.1b)

I: The CEO and/or governing body representative describes the long term vision and goals for the organization. (CIV.1b)

CIV.1	Strategic planning reflects the organizational mission and includes a comprehensive evaluation of both internal and external environments.

CIV.1a Current budgetary, business and marketing activities are integrated into the process.

CIV.1b An assessment of the organization's strengths, weaknesses, opportunities and threats is conducted on a periodic basis.

LEGEND:

D - DOCUMENTATION
I - INTERVIEW
O - OBSERVATION
S - SURVEY

CIV.2

D: The organization provides evidence that a current annual evaluation was conducted timely and in accordance with its organizational policies and process.(CIV.2a)

D: The annual evaluation report validates the inclusion of service/product, risk management, human resources and financial and operational components in the evaluation process. (CIV.2b)

I: Administrative/management personnel describe how the complexity of the organization relates to data collection and utilization. (CIV.2b)

D&I: Minutes and interview confirm that the annual evaluation report was presented to the appropriate advisory and governing bodies. (CIV.2d)

Note: The Medicare Certified home health agency must comply with CFR 484.16. 484.16(a), 484.52, 484.52(a). See Appendix I HH for a full text of the regulations and a cross-walk.

Note: The Medicare Certified hospice organization must comply with CFR 418.66. See Appendix IH for a full text of the regulations and a crosswalk.

CIV. 2 An Annual evaluation of the organization provides the basis for future planning.

CIV.2a Organizational policies drive the process for the annual program evaluation by an authorized group and identify the components to be evaluated.

CIV.2b The complexity of the organization and the scope of care, services, and products provided define the parameters for data collection and utilization and includes service/product, risk management, human resources and financial data.

CIV.2c Variances from usual and expected patterns of performance are analyzed and explained.

CIV.2d The Annual Evaluation Report is presented to advisory and governing bodies as appropriate.

CIV.2e The Annual Evaluation Report is retained as an administrative record.

CORE

SELF STUDY

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INTRODUCTION TO CORE SELF STUDY

The Community Health Accreditation Program, Inc. (CHAP) accreditation process is comprised of five steps:

1) Submission of an application and application fee
2) Submission of a signed contract accompanied by a pre-determined initial fee
3) Submission of a completed Self- Study
4) Comprehensive Site Visit by a team of professionals, the number of which is determined based on the size of the organization and complexity of services provided.
5) Submission of the Site Visit Report to the Board of Review for Review and Determination of Accreditation Status.

The Self-Study process is completed by the organization seeking CHAP Accreditation:

1) Prior to the initial site visit
2) Prior to the first visit of a new contract cycle

What is the Self-Study?

The Self-Study is a dynamic tool, used by organizations seeking CHAP Accreditation, which assists the organization in preparing for the on-site accreditation visit. The process involves a comprehensive internal self-assessment of the organization's:

- Structure and Function
- Quality of Services and Products provided
- Resources: Human, Financial and Physical
- Long Term Viability

Suggestions for the Completion of the Self-Study

CHAP recommends that a coordinating committee be appointed, comprised of representatives from each of the organization's programs and/or departments. Selection of a chairperson, who assumes oversight responsibilities for the group, will assure adherence to established time frames and keep the committee focused on achieving a positive accreditation outcome. CHAP recommends that Sections I, II, III, and IV of the CORE Self-Study be completed prior to completing the companion sections in the Service-Specific Standards in order to avoid duplicative responses. CHAP also recommends that the Standards of Excellence and Evidence Guidelines be utilized with the self-study as the organization assesses itself for compliance with the CHAP Standards.

Reaching group consensus on implementing a working agenda

- Strategies for completion of the document
- Assignment of responsible parties
- Estimated time frames for completion of various components of the process
- Processes for monitoring specific activities
- Meeting schedules and progress reports
- Projected date for the submission of the completed Self-Study document
- Retrenchment as necessary and indicated

Directions for Completion of the CORE Self-Study Document

The CORE Standards and Self Study are used in concert with the applicable service specific standards and self-study.

Complete the following documents of the Self-Study:

1) Contact Information Sheet
2) Organizational Data Sheet
3) Organizational Questions
4) Self-Study Spreadsheet

The eight (8) column format is defined as follows from left to right:

Column 1 CHAP Standards Alpha-numeric identifiers

Column 2 A description of the following:

- Underlying Principles
- Standard Statements
- Criterion Statements
- Elements of the Criterion (numeric identifier i.e., 1)
- Sub elements of a Criterion (identified by use of an alpha letter i.e., a)

Columns 3&4 Identification of documents/information/activities that are either "In Place" or "Not In Place"

- 3 = "Yes" If in place, check appropriate box
- 4 = "No" If not in place, check appropriate box

Column 5 "N/A" - Used to indicate that a Standard, Criterion, Element or Sub-element is not applicable to the organization completing the Self-Study. If N/A, check appropriate box

Column 6 "A/R" Indicates those standards/criterion which must have a substantiating document submitted as an attachment to the Self-Study. That designation will be included on the Self-Study by CHAP prior to being sent to your organization

Column 7 "A/O" – Attachment Optional. An attachment that may be designated by CHAP or the organization seeking accreditation

Column 8 Comment space for notations or points of clarification by the organization seeking accreditation by CHAP

Submission of Self-Study:

Submit self-study and required attachments to CHAP Site Visitor Coordinator, CHAP, Inc., 39 Broadway, Suite 710, New York, New York, 10006. Refer to the original contract letter for specific number of self-studies required to be submitted to CHAP.

In addition to the self-study required attachments, submit one (1) copy each of the following:

1. Copy of the structured framework for the investigation of target outcomes.
2. Copy of job description for each key position category
3. Template for Service Contracts (if available)
4. Financial Statements (audited/reviewed/internal)
   Balance sheet; Statement of Cash Flows; Income Statements and/or supplementary spreadsheets for the past three (3) years. Multi-unit organizations should send audited consolidated statements of the Corporate/ Parent organization.

CORE Self Study

Contact Information

For: _____
Name of Organization

Location: _____

_____

Contact: _____

Telephone: _____

E-mail: _____

Submission Date: _____

Note: This should be the first page of your Self Study.

Mail to: **Site Visit Coordinator**
CHAP, Inc.
39 Broadway, Suite 710
New York, NY 10006

ORGANIZATIONAL DATA SHEET
CORE

Administrative Profile
(Only include positions not included in service-specific organizational data sheets)

	*FTE Positions Budgeted**	*Current FTEs*	*Vacant Positions*	*Contract Staff*
Executive Staff:				
Supervisory Staff:				
Support Staff (office/clerical):				
Other (Specify)				
Other (Specify)				
Other (Specify)				

* FTE = Full time equivalent (40 hour week = 2,080 hours per year)

ORGANIZATIONAL DATA SHEET
CORE

Turnover Rates for Past Fiscal Year:

Category of Positions	*# of Individuals*	*Percent (%)*
Exec/Admin/Management staff		
Supervisory staff		
Direct care/service staff		
Professional		
Paraprofessional		
Technical		
Support staff (office/clerical)		
Other (specify)		
TOTAL		

ORGANIZATIONAL DATA SHEET (cont'd.)
CORE

Revenue/Expense:
(Last fiscal year)

Total annual revenue: $ _____

Total annual expense: $ _____

Insurance coverage maintained:

General liability:	$ _____	Malpractice:	$ _____
Directors & Officers liability:	$ _____	Workers Comp:	$ _____
Property & Casualty:	$ _____	Other (Specify)	$ _____

ORGANIZATIONAL DATA SHEET (cont'd.)
CORE

Service Data

Dates of last fiscal year: _____

Total unduplicated clients in last fiscal year: _____

Total volume services in last fiscal year: _____

Service Description

Types of Services/Products Provided by Organization:

_____

_____

_____

Description of Geographic Service Area:

_____

_____

_____

Service Volume Change Over Previous Three (3) Year Period:

_____

ORGANIZATIONAL QUESTIONS

CI. STRUCTURE & FUNCTION OF THE ORGANIZATION

1. **What is the organization's Governing Body?**
   Describe the structure and function.

2. **What responsibilities and activities are delegated to the Chief Executive by the Governing Body?**

3. **What mechanisms are employed to keep the Governing Body informed of organizational issues?**

CI. (cont'd.)

4. **How does the organization develop and implement policies?**

5. **What significant changes have occurred in the organization during the past two years? Please describe.**

CII. QUALITY OF SERVICES & PRODUCTS PROVIDED

1. **How does the organization use the results of performance improvement activities to make changes for all programs/services?**
   Describe for all programs/services seeking accreditation.

CIII. ADEQUATE RESOURCES

1. **How does the organization assess its need for adequate staff, physical space and financial resources for all programs/services?**
   Describe for all programs/services seeking accreditation.

CIV. LONG TERM VIABILITY

1. **Describe the challenges facing the organization's long term viability.**

2. **Describe how the organization is positioning itself to ensure future viability.**

	Description	IN PLACE					Comments
		YES	NO	N/A	A/R	A/O	
CI.1	STRUCTURE & FUNCTION						
CI.1	Published Mission statement identifies commitment to quality & consumer needs				X		
CI.1a	Programs & Services reflect organization's written mission						
CI.1b	Mission statement is reviewed/approved by GB every 36 months						
CI.2	Structure/functional mechanisms support the stated Mission						
CI.2a	Legal authority to operate & in compliance with local, state, and federal regulations						
CI.2b	Governance Structure is defined in legal documents specific to the organization.						
CI.2c	An identified governing body:						
	1) Assumes full legal authority/responsibility/accountability for organizational performance						
	2) Appoints a qualified administrator						
	3) Designates advisory group membership as applicable						
CI.2d	GB membership comprised of individuals with relevant expertise, business acumen, and professional relationships specific to the organization's stated mission				X		
CI.2e	GB members are oriented to the organization & are knowledgeable &responsive to key issues affecting the organization						
CI.2f	GB carries out responsibilities specific to the organization including:						
	1) Establishing policies consistent with organizational mission						
	2) Approving new/revised P&P's as indicated & necessary						
	3) Holding management accountable for the organization's solvency & finances						
	4) Approving budgets & capital expenditures						
	5) Selecting & evaluating the chief administrator						
	6) Evaluating organizational performance						
	7) Developing & approving strategic plan						
	8) Periodically reviewing legal & business documents, at least every 36 months (Article of Incorporation, By-laws, Legal Agreements)						
CI.2g	GB members & executive staff provide annual written disclosure of all professional &/or personal relationships or interests, direct or indirect, that might represent a conflict of interest. Signed annual disclosure statements are on file in the office.						
CI.2h	The GB complies with organizational by-laws or other legal documents.						
CI.2i	Accurate, complete, & signed minutes are kept of all official meetings of the GB						
	1) Actions taken are documented.						
	2) Minutes are distributed in accordance with organizational policy						
	3) Minutes are retained at least 5 years or consistent with state regulations.						
CI.3	Intra-organizational relationships are clearly defined						
CI.3a	Current organizational chart delineates lines of authority & accountability of all personnel				X		
CI.3b	Organizational chart is reviewed and changed as needed						
CI.3c	Personnel understand & use appropriate lines of authority as outlined in the organizational chart.						

	Description	IN PLACE					Comments
		YES	ND	N/A	A/R	A/D	
Cl.4	**Authority & responsibility for overall administration & management is vested in qualified individuals**						
Cl.4a	Chief executive/administrator's credentials include appropriate industry experience and knowledge of applicable local, state, and federal laws.						
Cl.4b	Qualifications for administrative & management positions are defined in writing & are consistent with scope of responsibility & complexity of the organization. Administrative/mgmt personnel have equivalent combinations of education/training/experience to qualify for assigned responsibilities				X		
Cl.4c	Qualified person is designated in writing to assume administrative responsibility in the absence of chief executive/administrator.				X		
Cl.4d	Admin. & mgmt. responsibilities are clearly defined & delegated as specified and include:						
	1) Organizing & directing the organization's ongoing operations to assure availability and provision of care & services						
	2) Implementing GB directives & organizational P&P's						
	3) Complying with applicable laws & regulations						
	4) Recruiting, employing & retaining qualified personnel to maintain appropriate staffing levels						
	5) Ensuring adequate staff education						
	6) Completing performance evaluations on subordinate staff in accordance with organizational policy						
	7) Directing/monitoring organizational Performance Improvement activities						
	8) Managing operations in accordance with established fiscal parameters						
	9) Planning, developing, implementing, administering & evaluating programs						
	10) Representing the organization to other groups, organizations & the general public						
	11) Ensuring the accuracy of public information materials						
	12) Informing the GB & staff of current organizational, community & industry trends						
Cl.5	**Organizational P&P's reflect an emphasis on quality & ethical practice & relate directly to the mission of the organization**						
Cl.5a	P&Ps are developed, revised, & reviewed annually to assure currency of information						
Cl.5b	Administrative P&Ps delineate administrative authority & responsibility for governance, planning, financial control & personnel. Policies include at a minimum:						
	1) Written disclosure of conflict of interest						
	2) Public disclosure of information				X		
	3) Responsibilities of ethical issues review group				X		
	4) Rights & responsibilities of clients				X		
	5) Internal & external complaint management				X		
	6) Exposure control plan				X		
	7) Formal safety program				X		
	8) Financial policies & procedures				X		
	9) Research activities/investigational studies as applicable						
Cl.5c	Operational P&Ps form the framework for planning, delivery & evaluation of care, & services provided. Policies include at a minimum:						
	1) Non-discrimination statement addressing admission of clients to service						
	2) Defined criteria for acceptance/non-acceptance of clients						
	3) Admission, continuation of service, & discharge						
	4) Standardized assessment process						

	Description	IN PLACE					Comments
		YES	NO	N/A	A/R	A/O	
	5) Referral to other providers of care/services						
	6) Medical orders, verbal orders & physician oversight as applicable						
	7) Emergency Service						
	8) After hours service						
	9) Confidentiality of protected health information				X		
	10) Emergency /disaster preparedness						
	11) Health, safety & security of staff during all hours of work						
	12) Services/products provided directly & under contract						
	13) Standards of practice for all disciplines as applicable				X		
	14) Standards of operations for all products as applicable						
	15) Infection control				X		
	16) Accepted medical term abbreviations						
Cl.5d	Personnel policies are developed & revised in response to organizational change & include:						
	1) Condition of employment						
	2) Respective obligations between employer & employee						
	3) Non-discrimination information						
	4) Grievance procedure						
	5) Employee orientation						
	6) Employer exit interviews						
	7) Maintenance of health reports & protected employee information						
	8) Employee record confidentiality & record retention						
	9) Recruitment, retention, & performance evaluation of staff						
Cl.5e	A written TB Exposure Control Plan is in compliance with the most current CDC applicable recommendations & requirements for occupational exposure to TB. The plan addresses:				X		
	1) Definition of employees at risk of occupational exposure to TB						
	2) Process for identifying suspected or confirmed cases of TB						
	3) Control of employee exposure when a client is suspected or confirmed as having infectious TB						
	4) Education & training to all employees to the hazards of exposure to TB at time of hire & annually thereafter .						
	5) Pre-employment & subsequent periodic TB screening of employees in accordance with written policy						
	6) Provision of follow-up care to employees exposed to TB						
	7) Provision of follow-up care to employees who convert to active disease						
	8) Provision of appropriate personal protective equipment when caring for a suspected/confirmed TB client						
	9) Provision of work practice oversight to minimize occupational exposure to TB						
	10) Adherence to reporting & record keeping requirements per state/federal law						
Cl.5f	Organizational P&P'S address the requirements of the Medical Device Act (MDA) & delineate the mechanisms for reporting incidents which result in serious injury, illness, or death						
	1) Reports are filed with the Federal Drug Administration (FDA) according to regulation						
	2) A designated person is responsible for ensuring compliance with reporting requirements						

	Description	IN PLACE					Comments
		YES	NO	N/A	A/R	A/O	
	3) Criteria for designation of reportable events are defined						
	4) Written protocols for investigation of events are defined						
	5) Investigative activities are initiated on a timely basis						
	6) Accurate documentation of findings include:						
	a) Investigative findings						
	b) Copies of reports sent to manufacturer						
	c) Copies of reports to the FDA						
	7) Retention & retrieval of findings & reports						
	8) In-service education on MDA reporting is provided to staff on an annual basis						
	a) Written curriculum outlines training content						
	b) Records of attendance are maintained						
CI.5g	Infection Control P&P's detail systems designed to promote the prevention & control of infections, monitor the occurrence of infections & evaluate the effectiveness of infection control practices				X		
	1) Current infection control practices & strategies						
	2) Identification & investigation of breaks in technique						
	3) Sources of infection						
	a) Nosocomial						
	b) Home acquired						
	c) Professional exposure						
	4) Types of infection						
	5) Modes of transmission of infection						
	6) Contributing causes of infection						
	7) Data collection, analysis, tracking, & trending of findings						
	8) Reporting requirements per state & federal regulations						
	9) Documented evidence of in-service education for staff includes:						
	a) Dates & times of programs						
	b) Curriculum outline of training content						
	c) Records of staff attendance						
	10) Client/family teaching						
	11) Use of personal protective equipment						
	12) Accepted hand hygiene techniques						
CI.5h	Administrative, financial, client, & personnel records are secured, retained, & retrievable in accordance with formal record retention policy that is in compliance with organizational policy & local/state/federal law				X		
	1) Minutes of all official meetings of GB are retained for at least 5 years						
	2) Client adult records are retained for at least 5 yrs after provision of service						
	3) Client records of minors are retained for at least 7 yrs after age of majority is reached						
	4) Mechanisms for client access & release of client records are defined						

	Description	IN PLACE					Comments
		YES	NO	N/A	A/R	A/D	
	5) Organization has defined authorization for client record documentation & entry & signature authorization/authentication for automated client record system in accordance with individual state law						
	6) Organization has defined process for maintaining safety & security of client records						
	7) Confidential records for employees experiencing an occupational exposure are retained for the duration of employment plus 30 yrs						
	8) Annual training records for exposure prone employees are retained for at least 3 yrs						
	9) Client records involved in litigation are retained until after settlement						
CI.5i	Staff members have access to P & Ps						
CI.6	**Information is provided to clients/families identifying the availability of organizational & community resources to assist in meeting client needs**				X		
CI.6a	Language specific written materials, as necessary & appropriate, are available for distribution to clients/families						
CI.6b	Interpretive services are provided, as indicated & necessary, to ensure accurate communication between client/family/caregiver & other types of health services personnel						
CI.7	**The organization's business, clinical, disease prevention & health promotion activities are conducted according to ethical standards**						
CI.7a	A group of qualified professionals is designated by the GB to review ethical issues as they arise						
CI.7b	Written P&Ps outlines responsibilities of the group & delineates the process for submitting ethical concerns & issues for action				X		
CI.7c	Meeting minutes clearly document group activities & are referred to the GB for review & final action as indicated & necessary						
CI.8	**The organization considers requests for research in the area of community/public health as appropriate**						
CI.8a	A mechanism is in place for reviewing, processing & approving internal & external research proposals						
CI.8b	Organizational P&Ps define parameters for participation in research activities & investigative studies						
	1) Research protocols, as applicable, for internally & externally sponsored activities are on file						
	2) Potential participants are provided written information regarding the nature, process, & benefits of the research outcomes						
	3) Risks associated with the project are clearly delineated						
CI.8c	Organizations participating in research or investigative studies ensure that clients & staff are fully informed						
CI.8d	Formal written consents for participants in research &/or investigative studies are obtained & retained on file in the organization						
CI.8e	New knowledge from internal or external research is integrated into practice, as applicable						

	Description	IN PLACE					Comments
		YES	NO	N/A	A/R	A/O	
CII	QUALITY OF SERVICES						
CII.1	Mission drives the activities of the organization & ensures public disclosure, client rights & ethical standards of business & clinical practice						
CII.1a	Public disclosure policy defines availability & accessibility of public information & includes:				X		
	1) Ownership information						
	2) Statement of organization's mission						
	3) Licensure & accreditation status, as applicable						
CII.1b	A written Client Bill of Rights recognizes, protects & promotes the right of each client to be treated with dignity and respect				X		
	1) Written P&Ps defines rights & responsibilities of clients						
	2) Clients receive notice of rights prior to receiving pre-planned care						
	3) Clients are knowledgeable of right to exercise rights at any time						
	4) Distribution of required information to clients is documented						
	5) The client/client's designated representative is authorized to exercise rights						
	6) Confidentiality of client record/data is maintained by the organization						
	7) Access to care/services is based upon non-discrimination						
	8) Clients are informed of right to voice complaints/grievances to the organization regarding treatment/care/service without fear of being subjected to discrimination or reprisal for doing so						
	9) Receive in writing the telephone numbers of the CHAP hot line, including hours of operation & purpose of the hot line to receive complaints or questions about the organization.						
	10) Clients are informed of right to participate in care/service plan development						
	11) Clients are informed verbally and in writing prior to start of care and as changes occur of billing/reimbursement methodologies, including fees for services/products provided, direct pay responsibilities, & notification of insurance coverage				X		
CII.1c	Written admission documents provided to client or the client's representative prior to the start of care or at the time of initiation of care/service ensure organizational compliance with Client Bill of Rights and other regulatory requirements				X		
CII.1d	Reasonable attempt is made & documented to ensure that client & family understand their rights & responsibilities which are reviewed with client prior to start of care or at time of initiation of care and periodically reviewed thereafter						
CII.2	Care, services & products are available to & accessible by the client/client's representative						
CII.2a	Care, services & products are provided within an established time frame, as specified by organizational policy, organizational standards, medical directives or individual physician orders. Consideration is given to the client &/or family needs in scheduling & providing care.				X		
CII.2b	Collaboration & networking with other providers enhance provision of care & services as applicable						
CII.2c	Supervisory & clinical/service staff demonstrate knowledge of organizational P& P for ensuring delivery of care, services, & products to clients						
CII.3	A geographic-specific plan defines protocols for prioritizing the delivery of care & services to clients & protects the safety of staff during disasters, emergencies and/or environmentally challenging situations				X		
CII.3a	Detailed written instructions are given to the client/family to ensure an appropriate & timely response on the part of the client/family in the event of an natural disaster, inclement weather & or other emergent event that might cause an interruption in the provision of services.				X		
CII.3b	Written protocols define management responsibilities in ensuring the safety & security of staff prior to or during an emergent event				X		
CII.3c	Staff are knowledgeable of the practices & procedures relative to emergency preparedness responsibilities & emergent events						
CII.4	Inter & intra organizational coordination is evident in the planning, implementation, monitoring & evaluation of care, & services provided						
CII.4a	Coordination between clinical/service, financial & operational components of the organization is evident						
CII.5	Client records, maintained for each client or client group, are utilized as a tool for coordination of services, as a legal document that is descriptive of care & services provided & as a resource document for billing & reimbursement						

	Description	IN PLACE					Comments
		YES	NO	N/A	A/R	A/D	
CII.5a	All protected health information or client records, hardcopy or automated, are kept confidential and safeguarded against loss or unauthorized use in accordance with organizational policy & local/state/federal regulations						
CII.5b	Clients have access to their records & are informed of the process						
CII.5c	Client record documentation provides client information specific to care & services/products provided, current client status & progress toward goals & outcomes of care						
CII.5d	Entries to client record documentation is made only by authorized staff & in accordance with organizational P&Ps				X		
CII.5e	Automated client record systems ensure consistent & ongoing protection of data						
CII.5f	The format for maintenance of client record is reviewed & updated as necessary						
CII.5g	Organizations with alternate sites ensure consistent documentation, communication, coordination & retrieval of significant administrative & client/family information						
CII.6	A comprehensive Performance Improvement process integrates the organization's mission & promotes an organizational-wide approach that selects, reviews & analyzes outcomes specific to organizational needs & scope of services/products.						
CII.6a	Quality is defined and measured in terms of client/service outcomes						
CII.6b	Specific outcomes are targeted for improvement or replication						
CII.6c	The organization develops a structured framework for the investigation of target outcomes						
CII.6d	The organization identifies outcomes to benchmark by utilizing internal standards/processes/protocols, practice/service guidelines, industry research &/or best practices						
CII.6e	The organization continually evaluates progress toward outcomes & identifies new areas to improve or replicate as indicated by results of data analysis						
CII.6f	A process for monitoring & measuring the satisfaction levels of clients is conducted at least annually				X		
CII.6g	Performance Improvement findings are:						
	1) Used to resolve identified problems						
	2) Used to improve quality of services/products						
	3) Incorporated into program planning/modification/enhancement						
CII.6h	Trends of Performance Improvement findings are reported to appropriate organizational committees & the GB						
CII.7	The health & well-being of employees & clients is promoted & enhanced through education, current application of infection control practices & implementation of appropriate safety measures.						
CII.7a	Adherence to regulatory requirements that address the health & safety of employees & clients & their protection from blood borne pathogens is validated						
	1) State &/or Federal OSHA mandates as applicable						
	2) CDC recommendations & guidelines						
CII.7b	The organization implements its written Exposure Control Plan						
CII.7c	The potential for occupational exposure is determined for all job classifications in accordance with state/federal & Occupational Health & Safety Administration (OSHA) mandate				X		
CII.7d	Adherence to the use of Standard Precautions by job classification is documented						
CII.7e	Adherence to work practice & engineering controls is evident in practice						
	1) Physical work sites are maintained in clean & sanitary condition						
	2) Use of disinfectant solutions						
	3) Handling, transporting, storage & processing of soiled/contaminated materials, supplies & equipment						
	4) Use of non-leak infectious waste containers as applicable						
	5) Identification & labeling of infectious waste as applicable						
CII.7f	Employer & employee responsibilities relating to Hepatitis B prophylaxis (HBV) are defined in writing & include:						
	1) HBV vaccination & exposure follow-up program						

	Description	IN PLACE					Comments
		YES	NO	N/A	A/R	A/O	
	2) Employer/employee responsibilities						
	3) Declination of HBV statement is signed by the employees as applicable, & filed in personnel health records						
	4) Complete & detailed documentation of all exposure events						
	5) Confidential records are maintained on HBV vaccination & post exposure follow-up						
CII.7g	Education & training programs ensure that:						
	1) New employee orientation addresses all aspects of the Exposure Control Plan						
	2) Annual training is mandated for all exposure prone employees based on applicable job classification						
CII.7h	The organization demonstrates compliance its Occupational Exposure Control policies, plan & procedures						
	1) HBV is provided at no cost to all employees, potentially subject to occupational exposure, within 10 working days of assignment						
	2) Provision of personal protective equipment as appropriate to all employees with the potential for an occupational exposure as determined by their job classification						
	3) A confidential medical evaluation & follow up care is offered to employees who experience an occupational exposure:						
	a) Counseling						
	b) Testing of source individual if allowable under local and/or state law						
	c) Blood testing of exposed employee with written consent, if medically indicated						
	4) Accurate, confidential, & timely documentation of:						
	a) Circumstances leading to exposure						
	b) Routes of exposure						
	c) Medical follow-up						
	d) Opportunity for counseling						
	e) Other related interventions as indicated & necessary						
CII.7i	The organization demonstrates compliance with its TB Exposure Control Plan						
CII.7j	The organization demonstrates compliance with its safety program to monitor environmental conditions for identifying potential hazards/risks				X		
CII.7k	A routine assessment is made of the client's living environment to identify & evaluate potential safety hazards related to physical space as applicable						
CII.7l	A system is in place for monitoring & reporting information related to adverse events that endanger the health & safety of clients &/or employees & predispose the organization to real or potential liability				X		
	1) Adverse Events & Serious Adverse Events are defined in organizational policy						
	2) Data is collected for all events, analyzed/tracked/ trended as a part of risk management						
	3) Corrective actions are implemented & evaluated as indicated & necessary						
	4) Adverse event reports detail each episode & are distributed to advisory boards & accrediting bodies as applicable						
CII.7m	The organization demonstrates compliance with its P & Ps for the Medical Device Act (MDA)						
CII.7n	The organization demonstrates compliance with its infection control P & Ps:						
CII.8	Client/family complaints/concerns are responded to & resolved in a timely manner						
CII.8a	The complaint process includes intake, investigation, corrective action as applicable, complaint resolution, written reports, organizational trending, & follow-up						
CII.8b	Resolution/outcome information is communicated to the complainant						
CII.8c	Staff are aware of mechanisms for receiving & resolving complaints						

	Description	IN PLACE					Comments
		YES	NO	N/A	A/R	A/O	
CIII.	ADEQUATE RESOURCES: HUMAN, FINANCIAL, & PHYSICAL						
CIII.1	The organization has adequate & appropriate human resources to meet caseload & workload demands						
CIII.1a	A non-discriminatory recruitment & selection process, as defined in P&Ps, is adhered to				X		
CIII.1b	Personnel are employed & assigned responsibilities commensurate with their education & experience						
CIII.1c	Job descriptions for each employee category delineate lines of authority & reporting responsibilities, duties to be performed & educational & experiential qualifications specific to the position				X		
CIII.1d	Employee turnover rates are monitored, tracked, & trended as applicable						
CIII.1e	The opportunity for exit conferences are:				X		
	1) Offered to terminating employees as applicable						
	2) Documented & trended as applicable						
CIII.1f	Personnel policies/conditions of employment are provided to employees::						
	1) At time of hire						
	2) Thereafter, as updates/revisions are needed						
CIII.1g	Evidence of the following employee information is maintained in accordance with organizational policy & regulatory guidelines:						
	1) Individual job qualifications						
	2) Verification of education/training						
	3) Certification for specialty areas of practice as applicable						
	4) Statement of formal training for non-professionals						
	5) Two (2) reference checks						
	6) Pre-employment interview(s)						
	7) Current license/certification as applicable						
	8) Validation of clinical competency skills testing as applicable						
	a) Time of hire						
	b) Annual						
	9) Validation of performance evaluation at end of probation & annually						
	10) Validation of malpractice coverage for independent contractors						
	11) Validation of completion of orientation (time of hire & re-assignment)						
	12) Validation of signed & dated confidentiality statements						
	13) Validation of in-service/continuing education participation as applicable						
	14) Validation of exit interview as applicable						
	15) Miscellaneous items per state, federal or organizational requirements						
	16) Criminal background checks in accordance with organization P & P and local and/or state law						
	17) Immigration & naturalization statement (I-9)						
CIII.1h	Specified personnel documents and employee health reports may be retained in separate files per organizational policy				X		
CIII.1i	An annual written performance evaluation process is completed on all employees by their respective supervisor & includes:						

	Description	IN PLACE					Comments
		YES	NO	N/A	A/R	A/O	
	1) Supervisor assessment of employee performance in accordance with established criteria (Job Description)						
	2) Achievement of previously established goals						
	3) On-site evaluation reports/competency testing for clinical/field/service staff						
	4) A signed, dated validation of the process by the employee & employer representative						
CIII.1j	An annual performance evaluation process provides an opportunity for active participation by employees through:						
	1) Employee development planning/new goal setting						
	2) Employee response to evaluation						
CIII.1k	A written plan details the orientation process for all new & reassigned employees which addresses applicable elements pertinent to each job classification				X		
CIII.1l	The organization shall provide in-service and staff development as needed and as required by local/state/federal regulations & national and/or professional standards as applicable				X		
CIII.1m	Personnel are provided with identification badges or are identified as working for the organization						
CIII.2	**Formal written contracts, executed by the primary organization with other professionals &/or other entities for the provision of care, services & products to clients of the primary organization, detail specific responsibilities of the parties involved**						
CIII.2a	Written service contracts with individuals &/or other entities are signed & dated by authorized principals of each party & are reviewed annually						
CIII.2b	The executed document stipulates the terms of the contract						
	1) Specific services/products to be provided						
	2) Contractor is required to adhere to applicable primary organization P&P's						
	3) Assurance by the contractor of the education, training, qualifications & identification of personnel designated to provide care, services & products						
	4) Mechanisms for the contractor parties to participate in Performance Improvement activities as applicable						
	5) Procedures for the documentation & submission of documented notes that verify the provision of services/products in accordance with the written service contract						
	6) Procedures for the submission of bills & related information & reimbursement for care, services & products provided						
	7) Effective dates of the contract, including terms of renewal &/or termination *N.B. Additional service specific contract elements are addressed under contracts in service specific standards*						
CIII.3	**The organization's sources of financial support are managed &monitored on an ongoing basis to ensure the availability of adequate funding**						
CIII.3a	Financial P&Ps govern fiscal activities of the organization						
CIII.3b	The chief financial manager has the appropriate qualifications, credentials & expertise to oversee, manage & direct the fiscal operations of the organization						
CIII.3c	Major participants in developing & monitoring the budgetary process include the GB, the chief executive, the chief financial manager, program directors & other designated staff as appropriate						
CIII.3d	The operating budget & operating capital expenditure plan is developed using methodologies commensurate with the scope & complexity of the organization's services, programs, & products & is used to forecast financial & operating successes & challenges						
CIII.3e	Financial management tools are used to provide operational feedback to administrative & management personnel, financial committees & the GB						
CIII.3f	Adequate insurance coverage is maintained				X		
CIII.3g	An annual external review is required & conducted				X		
CIII.4	**A financial management information system is used to document &monitor all financial components & provide appropriate & timely reports to all levels within the organization**						
CIII.4a	The financial reporting system produces detailed data re: actual transactions specific to care, services & products provided by each program including site/location activity						
CIII.4b	Periodic financial statements contain key financial ratios & show a reasonable match between revenue & expense line items				X		
CIII.4c	Internal financial controls are in effect						
	1) Internal audit procedures & annual review of budget are conducted						

	Description	IN PLACE					Comments
		YES	NO	N/A	A/R	A/D	
	2) Adherence to organizational financial P&Ps is monitored						
CIII.4d	Reimbursable services are billed on a timely basis in accordance with designated fee structures & are monitored, tracked, & aged						
CIII.4e	Payroll & vendor disbursements are recorded & processed in a structured & timely manner						
CIII.5	Physical facilities are adequate to support the operations						
CIII.5a	Physical facilities meet the OSHA (Federal/State), CDC, ADA &/or state or local regulations for environmental protection & safety of employees & clients						
CIII.6	A management information system is utilized to ensure accountability at all levels of the organization						
CIII.6a	A manual or automated system utilizes established standards & defined data elements for the collection & processing of information						

	Description	IN PLACE					Comments
		YES	NO	N/A	A/R	A/O	
CIV.IV	LONG-TERM VIABILITY						
CIV.1	Strategic planning reflects the organizational mission & includes a comprehensive evaluation of both internal & external environments				X		
CIV.1a	Current budgetary, business & marketing activities are integrated into the process						
CIV.1b	An assessment of the organization's strengths, weaknesses, opportunities & threats is conducted on a periodic basis						
CIV.2	An annual evaluation of the organization provides the basis for future planning				X		
CIV.2a	Organizational policies drive the process for the annual program evaluation by an authorized group & identify the components to be evaluated						
CIV.2b	The complexity of the organization & the scope of care, services & products provided define the parameters for data collection & utilization and includes:						
	1) Service/product data						
	2) Risk management data						
	3) Human resources data						
	4) Financial data						
CIV.2c	Variances from usual & expected patterns of performance are analyzed & explained						
CIV.2d	The Annual Evaluation Report is presented to advisory bodies & GB as appropriate						
CIV.2e	The Annual Evaluation Report is retained as an administrative record studies are obtained & retained on file in the organization						

PHARMACY

STANDARDS OF EXCELLENCE

TABLE OF CONTENTS

TABLE OF CONTENTS

INTRODUCTION TO CHAP PHARMACY STANDARDS

In keeping with its goal of elevating the quality of all community health care in the United States, the Community Health Accreditation Program, Inc. (CHAP) continually reviews and revises the "Standards of Excellence" to ensure currency with and relevance to the community health care industry. The service-specific Pharmacy Standards 2004 Edition are designed to:

- Establish standards of excellence for all types of Pharmacy services (Open Door, Long Term Care, Mail-Order, Internet, Specialty, Compounding, Infusion)
- Promote ease of application, interpretation and use of standards
- Emphasize the importance of the interests and rights of Pharmacy clients
- Strengthen the long-term viability of all types of Pharmacy organizations
- Advance the recognition of the Pharmacy organization as an integral component of the national health care delivery system

The re-engineered Pharmacy Standards of Excellence, 2004 Edition, address the scope, complexity and challenges of providing comprehensive Pharmacy services in a variety of community-based settings. When used in conjunction with the CORE Standards, 2004 Edition, compliance is ensured with:

- Pharmacy regulatory requirements
- Regulatory requirements that address the health and safety of employees and clients

CHAP standards incorporate most current professional, clinical, industry and regulatory standards and/or requirements.

Underlying Principles

Four key principles form the framework for the revised standards:

I. Structure and Function
II. Quality
III. Resources
IV. Long Term Viability

The four key "Underlying Principles" (UP) continue to drive each set of the CHAP Standards of Excellence. Sub-categories in each section further define the content. The four key underlying principles are used consistently throughout the CHAP accreditation documentation process in the Standards, Self-Study, Workbooks and Site Visit Reports.

UP I. THE ORGANIZATION'S STRUCTURE AND FUNCTION CONSISTENTLY SUPPORTS ITS CONSUMER ORIENTED MISSION AND PURPOSE.

A. Statement of Pharmacy Scope of Products/Services
B. Organizational Structure And Functional Mechanisms
C. Intra-Organizational Relationships
D. Pharmacy Program Director
E. Pharmacy Specific Policies and Procedures
F. Ethical Issues
G. Student Education/Research

UP II. THE ORGANIZATION CONSISTENTLY PROVIDES HIGH QUALITY SERVICES AND PRODUCTS.

A. Public Disclosure, Client Rights, Ethical Standards
B. Services Provided
C. Emergency Preparedness & Response
D. Access to Services/Inter & Intra Organization Coordination
E. Assessment, Plan of Care, Verbal Orders
F. Client Records
G. Effectiveness of Services
H. Health & Wellbeing of Employees & Clients
I. Complaints

UP III. THE ORGANIZATION HAS ADEQUATE HUMAN, FINANCIAL, AND PHYSICAL RESOURCES TO ACCOMPLISH ITS STATED MISSION AND PURPOSE.

A. Human Resources Support Workload Demand
B. Staffing Contracts
C. Financial Resources
D. Physical Facilities
E. Information Systems

UP IV. THE ORGANIZATION IS POSITIONED FOR LONG TERM VIABILITY.

A. Strategic/Operational Planning
B. Annual Evaluation of the Pharmacy Operations and Structure
C. Innovations

As you study and apply these standards to your own organization, give consideration to the following *"THEMES"* that flow through all sections of the CHAP Standards of Excellence and Self Studies.

Composition of a Standard

Each standard statement may be comprised of four (4) parts.

1. Standard statement - A blueprint for success that recognizes excellence
2. Criterion - A statement that defines in detail the requirements of the standard
3. Element - A component of each criterion that delineates requirements
4. Sub-element – Additional statements that provide more definition of selected elements.

Examples
Standard:.....HMEI.1
Criterion:.....HMEI.1a
Element:.....1)
Sub element:.....(a) (not all standards have sub-elements)

Main Sources of Evidence

D = Documents
I = Interviews
O = Observations
S = Surveys

Substantiation of Findings

Clarification
Verification
Quantification

Evidence Guidelines

The Standards are formatted with relevant Evidence Guidelines on pages opposite the standards. The evidence guidelines are not standards or criteria. They are intended to provide guidelines and examples of evidence to the organization and the CHAP site visitor which may be used to determine organizational compliance with the standards. The letter preceding each evidence guideline identifies one of four sources of information to be used by the site visitor in the accreditation process: D, I, O, S.

The Site Visit Report

The Site Visit Report is a written legal document that states the level of compliance by the Pharmacy organization with both the CORE and Pharmacy Standards of Excellence. The composition of the report includes a brief organizational profile, statements of organizational strengths and challenges and the written citations.

Citations include:

Commendation:	A statement indicating that the organization has significantly exceeded the requirements of a specific standard or criterion.
Required Action:	A statement indicating partial or total non-compliance with a CHAP standard or criterion. Organizations are required to make changes to comply with CHAP standard or criterion.
Recommendation:	A statement of advisement that identifies a potential problem related to a standard or criterion that may increase in scope and severity if not addressed. Organizations are not required to make changes but should give serious consideration to the recommendation.

DI.

THE PHARMACY ORGANIZATION'S STRUCTURE CONSISTENTLY SUPPORTS A CONSUMER ORIENTED MISSION AND PURPOSE

PHARMACY

LEGEND:

D - DOCUMENTATION
I - INTERVIEW
O - OBSERVATION
S - SURVEY

DI.1

D: A printed definition of the organization's scope of products and services is available. (DI.1)

D: Governing body minutes document actions taken on the scope of products and services statement:
(a) Review and approval within the past twelve months.
(b) Revisions and updates as applicable.
(DI.a)

I: Management and staff describe the process for making scope of products and services statement available upon request. (DI.1b)

DI.1	A written statement by the Pharmacy Organization identifies the scope of products and services provided to clients.

DI.1a The scope of services statement is periodically reviewed, revised and approved by the governing body but no less than every twelve (12) months.

DI.1b The pharmacy's scope of services statement is made available upon request to clients, referral sources and other interested parties.

LEGEND:

D - DOCUMENTATION
I - INTERVIEW
O - OBSERVATION
S - SURVEY

DI.2

D: **Required County/State/Federal licenses, authority documents, and Medicare/Medicaid/reimbursement certification (if applicable) are current as required. (DI.2a)**

Note: County/State specific licenses may include Sellers Permit, Occupational License, etc.

D: **Review of recent findings of other reviewing bodies confirm compliance. (DI.2a)**

D: **The disclosure statement is current, signed and dated by the chief executive and on file. (DI.2b)**

D: **Minutes or other formal governing body documents reflect that the governing body authorized an advisory committee. (DI.2c)**

Note: Advisory Committee may be the governing body as a whole, a subcommittee of the governing body or a separate committee.

D: **Membership in the advisory committee includes a physician, a pharmacist, a registered nurse and at least one community representative. (DI.2c)**

D: **Official documentation or minutes reflect annual review of policies and evaluation of the Pharmacy program. (DI.2c)**

DI.2	The Pharmacy Organization has the structure and functional mechanisms necessary to accomplish its stated scope of services.

DI.2a The Pharmacy Organization has the legal authority to operate and is in compliance with local, state and federal regulations.

1) State Board of Pharmacy License
2) Business License
3) DEA Narcotic License
4) d/b/a, Trade Name registration, if applicable
5) Tax ID number
6) Medicare & Medicaid provider numbers, where applicable
7) Specific county and state required authorities

DI.2b The Pharmacy Organization is required to prepare and maintain a current written disclosure statement signed by the chief executive, addressing applicable elements as frequently as required by state regulations but no less frequently than every three years.

1) Names and addresses of individuals or corporations having a combined direct or indirect ownership or controlling interest of 5% or more in the organization
2) Names and address of subcontractors in which the organization has a direct or indirect ownership of 5% or more
3) Names and addresses of individuals, who are related as spouse, parent, child or sibling to individuals described in (1) and (2) above
4) Names and addresses of individuals in (1), (2), and (3) above with an ownership or controlling interest in a Medicare or Medicaid facility
5) Names and addresses of officers, directors or partners
6) The circumstances of any criminal offense conviction involving Medicare/Medicaid programs on the part of any person(s) or organization(s) in (1), (2) or (3) above and/or, on the part of any managing employee of the organization
7) The dates of any changes in ownership or control during the previous twelve (12) months
8) The dates of anticipated changes of ownership or control in the next twelve (12) months

DI.2c An Advisory Committee of professionals is authorized by the governing body to advise the organization on policies and to evaluate the Pharmacy Program.

1) Responsibilities of the committee include establishment and annual review of pharmacy policies and participation in the annual evaluation of the Pharmacy program.
2) Membership of the committee includes a physician, a pharmacist, a registered nurse and at least one community representative who is not an employee
3) Committee meeting minutes reflect the committee's fulfillment of its responsibilities
4) The Advisory Committee meets at least once annually.

LEGEND:

D - DOCUMENTATION
I - INTERVIEW
O - OBSERVATION
S - SURVEY

DI.2 cont'd

I:	Management and staff describe and cite examples of how current clinical and organizational data are assessed and used in revision of policies and practices. (DI.2d)

DI.2d Systems exist for obtaining and integrating the most current information into the professional practice to be used in planning, evaluation and decision making in all aspects of the program.

LEGEND:

D - DOCUMENTATION
I - INTERVIEW
O - OBSERVATION
S - SURVEY

DI.3

D: A current organizational chart is available and clearly delineates the lines of authority and accountability for all organizational positions. (DI.3a)

I: Staff members are familiar with the organizational chart and state their individual lines of authority and accountability. (DI.3a,3b)

DI.3	Intra-organizational relationships of the Pharmacy Organization are clearly defined in writing.

DI.3a A current organizational chart illustrates the lines of authority and accountability for all administrative, professional, technical, clinical and clerical personnel.

DI.3b The complexity of the Pharmacy organization's administrative structure is appropriate for efficient delivery of product and service.

LEGEND:

D - DOCUMENTATION
I - INTERVIEW
O - OBSERVATION
S - SURVEY

DI.4

D: **Pharmacy Program Director's resume, diploma, reference checks and current professional license verify compliance with requirements for the position. (DI.4a, DI.4b)**

Note: The Pharmacy Program Director may be a regional position in multi-state organizations. In that instance, the Program Director would have a current active Pharmacist license in a state. The Pharmacist in Charge at the specific site will have an active Pharmacist license in that state. The Pharmacy Program Director and the Pharmacist in Charge may be the same or separate position in the organization..

I: **Pharmacy Program Director demonstrates knowledge of local, state and federal pharmacy regulations. (DI.4b)**

D: **The Pharmacy Program Director's job description and/or policies include responsibilities as specified in elements 1-11, or the responsibilities are clearly delegated to other specific positions. (DI.4c)**

I & O: **The Pharmacy Program Director demonstrates understanding of his/her role. (DI.4c)**

D: **Written policy and procedure defines assignment of administrative responsibilities in the absence of the Pharmacy Program Director. (DI.4d)**

I: **Designated alternate to the Director understands his/her role and describes experiences specific to the alternate roles. (DI.4d)**

Note: DI.4 may appear to be a duplication of CI.4; however, CI.4 pertains to the CEO of an organization, and DI.4 pertains to the Pharmacy Program Director, which may be the same or separate position in the organization.

DI.4	Authority and responsibility for the overall executive management of the Pharmacy Organization is vested in qualified individuals.

DI.4a The Pharmacy Program Director is a graduate of a pharmacy program accredited by the American Council of Pharmaceutical Education or has passed a Foreign Pharmacy Graduate Equivalency Examination given by the National Association of Boards of Pharmacy, is currently licensed as a Pharmacist in the state.

DI.4b A qualified pharmacist with appropriate knowledge, expertise and experience is responsible for the management, direction, coordination and general supervision of all professional services.

DI.4c The Pharmacy Program Director is responsible for the following areas either directly or by clear delegation:

1) Organizing and directing the Pharmacy program's operations to assure the availability of services and products provided
2) Assuring adequate inventory of pharmaceuticals and supplies necessary to compound and dispense prescriptions appropriately, including periodic inspection for outdated products.
3) Assuring all equipment utilized in the delivery of the organization's products and services is properly maintained
4) Assuring pharmacy services are provided in compliance with applicable laws, regulations, accreditation standards and ethical standards of practice
5) Assuring adequate and appropriate staffing, including recruitment, orientation, in-service education and completion of annual performance appraisal
6) Coordinating with other program areas and managers as appropriate, consistent with organizational structure
7) Assuring the implementation of a pharmacy performance improvement program including evaluation of the home pharmacy program services
8) Assuring Drug Control system consistent with policies and regulatory requirements
9) Assuring Drug Dispensing system consistent with policies and regulatory requirements
10) Assuring appropriate pharmacy supervision at all times
11) Assuring safe and appropriate service policies are developed and implemented

DI.4d A qualified individual is designated in writing to act in the absence of the Pharmacy Director.

LEGEND:

D - DOCUMENTATION
I - INTERVIEW
O - OBSERVATION
S - SURVEY

DI.5

D: Policies reflect the current practice, professional standards of Service, and scope of service.(DI.5a)

D: Pharmacy administrative policies and procedures at a minimum address items 1-4. (DI.5b)

D: Pharmacy operational policies and procedures at a minimum address items 1– 25. (DI.5c)

D: Policy is available and includes temperature, light and security. (DI.5c.1)

D: Policy is available when the pharmacy has a contractual relationship with a nursing agency. (DI.5c.8)

DI.5	Pharmacy policies and procedures reflect an emphasis on quality and ethical practice, relate directly to the scope of the Pharmacy program, and ensure client rights, and ethical standards of business and clinical practice.

DI.5a Organizational literature, policies and procedures accurately reflect the current practice, current professional standards of service and scope of the Pharmacy program.

DI.5b Pharmacy Program administrative policies and procedures include:

1) Regulatory Compliance
2) Capital Short-fall Contingency Plan
3) Pharmacy Reference Materials
4) Annual Evaluation

DI.5c Pharmacy Program operational policies and procedures covering the scope of services provided are developed and include at a minimum:

1) Storage of final pharmaceutical products
2) First dose new drug administration
3) Handling investigational drugs
4) Client/caregiver instruction
5) Timely assessment of client eligibility and provision of service
6) Notification of referral source if client does not meet admission criteria
7) Delivery of services/products, as applicable
8) Contents, dispensing and maintenance of infusion emergency kits
9) Acquisition, storage, disposition & dispensing of controlled substances
10) Selection, maintenance, use & control of infusion control devices for drug administration, as applicable
11) Client identification confirmation
12) Availability of latex-free supplies
13) Prescription labeling
14) Materials/Inventory Management
15) Equipment cleaning, testing and tracking
16) After Hours Coverage
17) Dispensing Records
18) Sterile Admixture Procedures for monitoring for medication errors, surface testing, environmental air sampling and product sterility
19) Preparation of injectables from sterile solutions
20) Preparation of injectables from non-sterile powders
21) Preparation of respiratory drugs from non-sterile powders
22) Clinical competency testing
23) Competency testing of sterile product preparation
24) Medication Error
25) Recall

LEGEND:

D - DOCUMENTATION
I - INTERVIEW
O - OBSERVATION
S - SURVEY

DI.5 cont'd

D: Pharmacy clinical policies and procedures at a minimum address items 1 –6. (DI.5d)

D: Pharmacy quality improvement policies and procedures at a minimum address items 1-4. (DI.5e)

D: Written policy is available for first dose drug. (DI.5f)

DI.5d Clinical policies and procedures consistent with professional standards of practice are developed and include at a minimum the following:

1) Client Assessment
2) Medication Assessment
3) Drug Profile Review
4) Care Planning, as appropriate
5) Development of a comprehensive care plan
6) Clinical monitoring

DI.5e Quality Improvement policies and procedures consistent with professional practice and regulatory mandates are developed and include at a minimum:

1) Performance Improvement Plan
2) Structure and routine maintenance of compounding areas
3) Maintenance of Laminar Flow Hood
4) Infection control, safety for preparation, dispensing, disposal of pharmaceuticals

DI.5f Policies identify when a physician or other qualified professional is required to be present for the administration of the first dose of a new drug to detect, monitor and respond to adverse drug reactions.

LEGEND:

D - DOCUMENTATION
I - INTERVIEW
O - OBSERVATION
S - SURVEY

DI.6

D:	Meeting minutes document discussions of and actions taken by the group, as applicable. (DI.6a)
I &O:	Staff demonstrates knowledgeable of and compliance with reimbursement and regulatory guidelines. (DI.6b)

DI.6	The Pharmacy Organization's business and clinical activities are conducted according to ethical standards.

DI.6a A designated and qualified group of professionals/individuals address ethical issues relating to the business and clinical practices of the Pharmacy Organization. The issues include but are not limited to:

1) Care delivery issues
2) Product and service related issues
3) Billing and collecting issues
4) Medical necessity authorization issues
5) Statistical data trending and tracking issues

DI.6b Staff are knowledgeable about and carry out their responsibilities for providing products and services in accordance with reimbursement and regulatory guidelines.

LEGEND:

D - DOCUMENTATION
I - INTERVIEW
O - OBSERVATION
S - SURVEY

DI.7

I: Pharmacy Director/pharmacists describe the process for assuring that clients are fully informed and provide written consent prior to participating in research or investigative studies. (DI.7a)

D: Written contract or agreements pertaining to Pharmacy educational experiences for non-employees (i.e., students) exist as applicable. (DI.7b)

D & I: Documents and interviews validate that current research initiatives exist as applicable. (DI.7c)

D & I: Pharmacy employees publish research findings as applicable. (DI.7d)

DI.7	The Pharmacy Organization contributes to the development and expansion of knowledge in Pharmacy practice, as appropriate.

DI.7a	A Pharmacy Organization participating in research or investigative studies ensures that clients are fully informed and provide written consent.
DI.7b	Arrangements for student education experiences are formalized in written contracts or agreements that specify the responsibilities of the Pharmacy organization and the educational institution.
DI.7c	The Pharmacy organization demonstrates a positive attitude regarding research initiatives and considers requests for research in the area of pharmaceutical practice as appropriate.
DI.7d	The Pharmacy organization encourages the publication of significant outcomes related to the management and practice of pharmacy.

DII.

THE PHARMACY ORGANIZATION CONSISTENTLY PROVIDES HIGH QUALITY PRODUCTS AND SERVICES

LEGEND:

D - DOCUMENTATION
I - INTERVIEW
O - OBSERVATION
S - SURVEY

DII.1

D: Current Public Disclosure policy includes the element of DII.1a, if applicable, in addition to the elements of CII.1a. (DII.1a)

D: The Client Bill of Rights statement and/or other admission documents includes elements of DII.1b in addition to the elements of CII.1b . (DII.1b)

D: Record review confirms that the Client Bill of Rights is signed by the client or client representative and is filed in the record. (DII.1c)

O: Observation of the open door pharmacy validates that the Client Bill of Rights is posted in a public area. (DII.1d)

D: Record review validates that pharmacy products and services are provided to clients consistent with the organization's stated scope of service. (DII.1e)

DII.1	The Scope of Services drives the activities of the Pharmacy Organization and ensures public disclosure, client rights, and ethical standards of business and clinical practice.

DII.1a The written public disclosure policy makes the Annual Report for C Corporations, if applicable, available to the public on request.

DII.1b A written Client Bill of Rights statement or other written admission documents are provided to the client or the client's representative at the start of care or at the time of initiation of care and include the right to be fully informed of:

1) Services and products being provided
2) Organization's ownership and control
3) Names and qualifications of individuals providing products and services

And the right to:

4) Participate in one's own care
5) Continuity of products and services
6) Education about the products and services to be provided
7) Refuse part or all of the products and services to be provided
8) Receive products and services in a timely manner and in accordance with organizational policy
9) Be referred to another organization
10) Be free from abuse or exploitation of any kind
11) Receive information, both verbal and written, in an understandable format.

DII.1c The Client Bill of Rights is signed by the client or a representative of the client and made a permanent part of the client's record.

DII.1d For clients receiving open door pharmacy services, the Client Bill of Rights is posted in a public area accessible to those clients.

DII.1e The Pharmacy organization's products and services are provided in accordance with the organization's scope of services.

1) Statistical reports confirm that products and services are provided consistent with the Pharmacy organization's scope of services.
2) Staff at all levels are knowledgeable about and support the Pharmacy organization's mission and scope of services.

LEGEND:

D - DOCUMENTATION
I - INTERVIEW
O - OBSERVATION
S - SURVEY

DII.2

I & O: Interview and observation of practice confirms that the pharmacy organization is providing services as defined in DII.2a.

D: Job descriptions and/or other policies identify duties and responsibilities of each discipline, which are consistent with national practice standards. (DII.2b)

I & O: Interviews and direct observation of staff in practice confirms staff understanding and fulfillment of responsibilities. (DII.2b)

D: Clinical record documentation by respective disciplines verifies fulfillment of assigned responsibilities. (DII.2b)

DII.2	Pharmacy services are provided in accordance with organizational policies and procedures, to clients in their place of residence, and may include dispensing at the pharmacy site, transported delivery to home/client site or mailed delivery.

DII.2a Pharmacy services include but are not limited to:

1) Interpretation and evaluation of the prescription order
2) Drug product selection, compounding, dispensing, storage
3) Distribution of drugs and devices
4) Advising the prescriber and other health care professionals, the client and/or caregiver as to therapeutic actions, utilization and possible adverse reactions and interactions in order to encourage a positive client outcome.

DII.2b Pharmacy services are provided by or under the direction and supervision of a qualified pharmacist.

1) Professional pharmacy service is provided by a registered pharmacist and include:
    (a) Overseeing the drug control system including:
        1) Receipt of prescription drugs and prescription orders
        2) Storage of medications
        3) Packaging of medications
        4) Preparation and dispensing of prescriptions
        5) Labeling
        6) Preparation of prescriptions for delivery
    (b) Instruction/counseling clients and caregivers regarding specific drug therapy including possible adverse reactions and/or interactions
    (c) Providing information regarding the safe and appropriate use of medications to other health care professional
    (d) Identifying appropriate outcomes of drug therapy
    (e) Consulting on drug therapy and coordinating with other health care professionals
    (f) Monitoring and documenting ongoing drug therapy including the assessment of:
        1) The therapeutic appropriateness of the choice of drug(s)
        2) Therapeutic duplication in the client's drug routine
        3) Appropriateness of the dose, frequency and route of administration
        4) Adherence to drug regimen
        5) Potential drug, food or diagnostic test interactions of disease limitations to drug use
        6) Laboratory or clinical monitoring methods to detect drug effectiveness, side effects, toxicity or adverse effects
        7) Preparing and maintaining clinical records
    (g) Prescribing activities consistent with state/federal regulations.

2) Pharmacy technical services are provided by pharmacy technicians who have been trained for all tasks performed in compliance with state law, job description and organizational policy.

LEGEND:

D - DOCUMENTATION
I - INTERVIEW
O - OBSERVATION
S - SURVEY

DII.2 cont'd.

I: Procedures for ensuring availability of drugs, supplies and Equipment are described. (DII.2c)

I: Job descriptions and/or policies include the indicated delivery personnel responsibilities (DII.2d)

I & O: Interviews and direct observation of delivery services during home visits confirms staff understanding and fulfillment of responsibilities. (DII.2d)

I: Clients relate satisfaction with delivery services. (DII.2d)

I: Procedures for ensuring availability of drugs, supplies and infusion devices when not available from the organization are described. (DII.2e, DII.2f)

DII.2c The Pharmacy Program provides pharmaceutical care, related supplies and equipment to clients.

DII.2d Delivery services are provided directly or by arrangement in compliance with laws and regulations and include:

1) Safe and clean transport of pharmaceuticals and supplies to and from client homes/designated sites.
2) Timely delivery of pharmaceuticals and supplies
3) Record keeping
4) Setting up equipment in client homes, if applicable

DII.2e The organization has a process in place for assuring the availability of drug and supplies to clients in their designated sites not available from the organization.

DII.2f The organization has a process in place for assuring the provision of infusion devices to clients in their homes/designated sites when not available from the organization.

LEGEND:

D - DOCUMENTATION
I - INTERVIEW
O - OBSERVATION
S - SURVEY

DII.3

I: Staff describe how necessary services (pharmacy and delivery) are made available to clients at all times (on-call practices). (DII.3a)

D: Review of documents (complaint log, client satisfaction survey, on-call logs) validate that response times are consistent with policies and meet client needs. (DII.3a)

D & I: An on-call plan is available, and staff describe the on-call plan. (DII.3b)

O: Testing of the on-call plan validates that the organization is in compliance with its on-call coverage plan and policy. (DII.3b)

I: Client/family describes service availability after hours. (DII.3c)

D: Written contingency plan protocols are available and include items 1 – 3. (DII.3d)

DII.3	Clinical services and products are accessible and available to clients on an emergency basis 24 hours a day, 7 days a week.

DII.3a The Pharmacy Organization is accessible and responsive to the needs of Clients during normal work hours and after hours which includes:

1) Timely telephone response
2) Timely on-site response, if indicated
3) Product and service delivery prior to scheduled use

DII.3b There is a plan for on-call coverage for after hours, weekends and holidays.

DII.3c Clients are informed of the process for accessing service during normal work hours and after hours.

DII.3d Written contingency plans delineate protocols for prioritizing delivery of product and services to clients including:

1) Disaster preparedness
2) Inclement weather events
3) Unexpected critical staffing deficits

LEGEND:

D - DOCUMENTATION
I - INTERVIEW
O - OBSERVATION
S - SURVEY

DII.4

D: Written policy identifies admission criteria and referral process when the organization does not provide the needed product or service. (DII.4a)

D: Policies and procedures define the responsibilities of the pharmacists, and record review confirms documentation by the pharmacist. (DII.4b)

O: Observation validates assumption/fulfillment of responsibilities. (DII.4b)

D: Policies and/or procedures define the responsibilities for service coordination. (DII.4c, DII.4d)

D: Review of records confirms that care coordination activities are performed. (DII.4c, DII.4d)

Note: Appropriate referrals involves referrals for additional services as indicated. (DII.4d.4)

D: Client records document interdisciplinary coordination as appropriate. (DII.4 e)

I & O: Pharmacists indicate how drug profile information is made accessible to other appropriate professionals, the mechanisms for coordination, the procedures for coordinating delivery of medications, equipment and supplies and that that they are delivered and available as appropriate. (DII.4e)

DII.4	The Pharmacy Organization admits clients whose service needs can be met and ensures continuity of care/service through coordination of client services.

DII.4a Clients are admitted to service and continued on service, based on the reasonable expectation that their needs can adequately and safely be met by the program.

DII.4b A pharmacist assumes responsibility for planning, implementing therapy, evaluating the outcomes of therapy provided as applicable and documenting in the client record.

DII.4c Care is coordinated for each client by the pharmacist and includes at a minimum:

1) Periodic verbal, telephone or electronic communication with other professionals involved in the care of the client
2) Timely documentation of the coordination of care activities
3) Involvement of the client/client representative when indicated

DII.4d For other than open door pharmacies, care coordination includes elements 1-3 of DII.4c plus the following additional components:

1) Initial assessment of the client, family and, if applicable, the home environment
2) Development of a plan of care
3) Determination of expected outcomes
4) Appropriate referral and follow up
5) Implementation of the care plan
6) Ongoing evaluation
7) Plan of termination of care

DII.4e The pharmacist works collaboratively with other health care professionals to assure coordination of care.

1) The client drug profile information is available to professionals participating in the care of the client:

   a) at a minimum, during operating hours for all pharmacies
   b) at all times, including after hours for infusion pharmacies

2) The delivery of medications, equipment, and supplies is coordinated with other professionals involved with the care of the client to ensure that proper products and supplies are available when needed.

LEGEND:

D - DOCUMENTATION
I - INTERVIEW
O - OBSERVATION
S - SURVEY

DII.5

D: Client assessment policies and record review validate the inclusion of specified items for all pharmacies. (DII.5a)

D: Client assessment policies and record review validate the inclusion of specified items in DII.5a and DII.5b for infusion and long term care pharmacies. (DII.5b)

D: Medication assessment policy and record review validate the inclusion of elements 1-6. (DII.5c)

D, I &O: Interview, observation and record review confirm that client assessments and medication assessments are conducted prior to dispensing. (DII.5a,DII.5b,DII.5c)

D: Policies establish mechanisms for obtaining written physician verification of and approval for verbal orders. (DII.5d)

D: Record review documents that required prescriptions were received prior to dispensing medications. (DII.5d)

D: Record review documents that verbal orders are taken and signed by the Pharmacist prior to filling orders. (DII.5d)

DII.5	The Pharmacy Organization defines the plan of care process, including assessments, physician oversight, dispensing and client training.

DII.5a An initial client assessment is made by the pharmacist prior to dispensing which includes at a minimum:

1) Name, address, telephone number, gender, age/date of birth of client
2) Allergies/sensitivities of client
3) Medication Order
4) Physician name, telephone number

DII.5b For infusion and long term care pharmacies, an initial client assessment is made by the pharmacist prior to dispensing which includes elements 1-4 of DII.5a plus the following additional components as appropriate:

1) Chief Complaint/Medical history/Diagnosis
2) Height and weight of client
3) Client Infection, Sensitivities obtained as available
4) Significant Lab Results

DII.5c A medication assessment is made by the pharmacist prior to dispensing which includes at a minimum:

1) Potential drug interaction
2) Potential for poly-pharmacy
3) Appropriate dose and frequency
4) Appropriate time of administration
5) Appropriate route and method of administration
6) Appropriate infusion device of administration, if applicable

DII.5d Pharmaceuticals are dispensed according to the prescription of a physician or physician designee legally authorized to prescribe in compliance with state regulation:

1) Written, verbal or faxed prescriptions are available to the pharmacist before dispensing the medication
2) Verbal orders taken from a physician or physician designee are recorded and signed by the pharmacist prior to filling the medication order

LEGEND:

D - DOCUMENTATION
I - INTERVIEW
O - OBSERVATION
S - SURVEY

DII.5 cont'd

D: Written policy is available and includes elements 1-11. (DII.5e)

D: Drug labels include the indicated items. (DII.5e)

D: Plans of care are available for each client and include items 1-6. (DII.5f)

Note: Review by physician may include review of orders, copies of plans of care mailed/faxed to physician. (DII.5f.6)

D: Written policy and procedure define the process for confirming client Identification. (DII.5g)

I & O: Pharmacy and delivery staff explain the process for confirming client identification prior to dispensing. (DII.5g)

D: Policies and procedures with specifications detailed are available for emergencies for pharmacy infusion services. (DII.5h)

I: Staff are familiar with emergency procedures and provide examples of their appropriate use. (DII.5h)

D: Drug information and instructional materials are prepared for all types of products and services provided. (DII.5i)

D: Review of documents validates that the client or caregiver was instructed in self-administration of therapy when self-administration was indicated. (DII.5j)

D: Client training/education is documented. (DII.5i, DII.5j)

I & O: Clients understand their regimes. (DII.5i, DII.5j)

DII.5e All pharmaceutical products dispensed to clients are appropriately labeled according to state and federal regulations and, at a minimum, include:

1) Name, address and telephone number of the pharmacy
2) Date the prescription was dispensed
3) Expiration date of the medication
4) Pharmacy's prescription number
5) Client's full name
6) Name of the drug, brand, strength, if applicable, and the amount dispensed
7) Directions for use
8) Prescriber's name
9) Other pertinent information or cautionary labels
10) Rate, route and method of administration
11) For IV mixture drugs, rate of administration and expiration date of the fluid

DII.5f A comprehensive plan of care is developed by infusion pharmacies which includes:

1) Establishment of Therapy Specific Goals
2) Determination of Expected Outcomes
3) Determination of Educational Needs
4) Establishment of Monitoring Plan
5) Determination of Achievement of Goals/Outcomes
6) Periodic Review by Prescribing Physician

DII.5g Client identification is confirmed prior to dispensing.

DII.5h For pharmacy infusion services, there are policies and procedures for emergency situations including, ordering of emergency kits with appropriate drugs by the physician and placement of these kits in the client's home, where appropriate.

DII.5i Drug information and instructional materials for administration are provided to the client or client caregiver at the time of dispensing.

DII.5j Client training/education in self-administration is provided upon initiation of therapy, as applicable

LEGEND:

D - DOCUMENTATION
I - INTERVIEW
O - OBSERVATION
S - SURVEY

DII.6

D: Client records document that appropriate clinical services were provided to clients. (DII.6a)

D: Client records are current and include elements 1-4 . (DII.6a)

D: Client records document adherence to all clinical written policies and procedures. (DII.6a)

D: Client drug profiles are current and include items 1. a– h. (DII.6a.1)

D: Pharmacy dispensing records include items 2.a-k. (DII.6a.2)

D Records document adherence to first dose policy for new drug therapies. (DII.6a.2)

D: Pharmacy dispensing records for other than open door pharmacies include items a-k of DII.6a.2 and elements a-d of DII.6a.3. (DII.6a.3)

Note: Compounding instructions may be found in protocols, policies and/or specific instructional forms. (DII.6a.3c)

Documentation exists that a pharmacist oversees the process for dispensing, i.e., Pharmacist signature/initials on the label, on the compounding sheet, etc.(DII.6a.3d)

D: Narcotic records include items specified. (DII.6a.4)

I & O: Controlled substance records are maintained in compliance with state, federal and practice regulations. (DII.6a.4)

DII.6	Client records are maintained for each client and are utilized as a tool for coordination of services, as legal documentation of products and services provided and as a basis for billing and reimbursement procedures.

DII.6a Adequate and appropriate pharmacy records are maintained

1) Drug profiles are maintained for all clients and include the following information:

   (a) Name, gender, birth date and weight (when appropriate)
   (b) Address and client identification
   (c) Allergies or sensitivities
   (d) Diagnosis
   (e) Current drug regimen
   (f) Dosages
   (g) Relevant clinical information regarding drug therapy
   (h) Physician's name

2) Dispensing records are maintained for pharmaceuticals which include:

   (a) Client's identification, name and address
   (b) Name of medication
   (c) Strength and dosage form
   (d) Quantity dispensed
   (e) Physicians' name
   (f) Dispensing pharmacist/technician identification
   (g) Prescription number
   (h) Date dispensed
   (i) Directions for use
   (j) Expiration date
   (k) Number of refills authorized

3) Dispensing records for other than open door pharmacies are maintained for pharmaceuticals which include elements a-k of DII.6a2 plus the following:

   (a) Lot number(s) of drugs
   (b) Date of the addition(s) to intravenous admixture drugs
   (c) Special compounding instructions as applicable
   (d) Documentation of verification procedures

4) Controlled substance records are maintained in accordance with state, federal and practice regulations documenting that:

   (a) A controlled substance inventory is performed in compliance with state or federal regulation.
   (b) The pharmacist in charge is held accountable for the exact count of Schedule II pharmaceuticals
   (c) The pharmacist in charge is held accountable for an approximate count of Schedule III, IV, and V pharmaceuticals.

LEGEND:

D - DOCUMENTATION
I - INTERVIEW
O - OBSERVATION
S - SURVEY

DII.6 cont'd.

D: Policy is current and describes signature authentication. (DII.6b)

I: Records/system administrator describes the inclusion of the 9 items in the ongoing process of ensuring protection of data. (DII.6b)

O: Pharmacy staff protect data consistent with policy and state law. (DII.6b)

I & O: A back-up and storage system is in place. (DII.6b)

DII.6b Automated clinical record systems ensure consistent and ongoing protection of data.

1) Written policy describes signature authentication in accordance with individual state law
2) Safeguards prevent unauthorized access to inputted information
3) Individual and protected access codes are assigned to individuals designated to perform data entry
4) Automated programs designate and control areas of access by authorized personnel based on a personal identifier and position in the organization
5) The computer's internal clock designates date and time of entries
6) Automated controls prevent a change in entry, allowing only corrections
7) Hardcopies of automated data are retrievable by designated personnel
8) A system for validation of inputted data is in place
9) An automated system for backup and storage of data is controlled, and the data is stored in a safe environmental place.

LEGEND:

D - DOCUMENTATION
I - INTERVIEW
O - OBSERVATION
S - SURVEY

DII.7

I: The Pharmacy Director describes the performance improvement process for the pharmacy program. (DII.7a)

D: Evidence exists of utilization of performance improvement findings to resolve problems and improve quality of service/products. (DII.7a)

D: The performance improvement program include items specified in DII.7a.

D: The performance improvement plan includes items specified in DII.7b.

D: Evidence exists of monitoring and analysis of findings as specified in DII.7c.

I: Pharmacy Director and staff describe use of findings to identify problems and to improve performance. (DII.7c)

D: Staff orientation and in-service programs validate discussion of improvement program and indicators. (DII.7d)

D & I: When the pharmacy is part of a larger organization, evidence is provided demonstrating integration of quality improvement plans. (DII.7e)

DII.7	The adequacy, appropriateness, effectiveness and outcomes of products, services and supplies provided are routinely assessed.

DII.7a The Pharmacy Program has a formalized quality improvement program which is designed to:

1) Identify desired outcomes
2) Identify strategic and at-risk activities
3) Establish monitoring parameters for these activities
4) Establish minimal standards or criteria to be met
5) Describe methods used to improve the quality of service and to achieve the desired outcomes.

DII.7b The Pharmacy Program has a written performance improvement plan which includes:

1) Description of specific monitoring and evaluation activities
2) Specification of how results are to be reported and evaluated
3) Identification of appropriate follow-up mechanisms when thresholds are exceeded
4) Delineation of individual responsibilities for each aspect of the program.

DII.7c The Pharmacy Program's performance improvement program includes but is not limited to:

1) Monitoring for medication errors
2) Monitoring and analysis of the findings from surface testing, environmental air sampling and end product testing that includes sterility and pyrogens.

DII.7d Staff orientation and in-service programs integrate a focus on quality.

DII.7e The Pharmacy Program's performance improvement plan is integrated into the overall organizational quality improvement plan, as applicable.

LEGEND:

D - DOCUMENTATION
I - INTERVIEW
O - OBSERVATION
S - SURVEY

DII.8

D: Written policies exist and include items 1-10. (DII.8a)

D: Observation of staff performing responsibilities confirms that staff adhere to infection control and safety policies and procedures. (DII.8a)

D: Record review confirms that home environment assessments were conducted when indicated and that safety hazards were identified and precautionary instructions were provided to the client and documented. (DII.8b)

D: Policy requires the designated stipulation for the disposal of controlled substances. (DII.8c.1)

D: Records confirm adherence to policy. (DII.8c.1)

D: A Material Safety Data Sheet clearly outlines protocols for disposal of hazardous products. (DII.8c.2)

O: The Material Safety Data Sheet is available in the pharmacy. (DII.8c.2)

Note: The Material Safety Data Sheet information may be available on the pharmacy website as long as each pharmacy employee has access to the information.

D: Written instructions regarding disposition of hazardous substances in homes are provided to appropriate clients. (DII.8c.3)

I: Staff and client are aware of disposition procedures for hazardous Substances, if indicated. (DII.8c.3)

D. Records confirm adherence to policy and regulation. (DII.8c.4)

D: Client instructions regarding preparation of sterile solutions, storage methods, and durations are documented. (DII.8d)

I: Clients preparing sterile solutions at home are able to describe appropriate preparation and storage precautions. (DII.8d)

DII.8	The health and well being of employees and clients is promoted and maintained through education and implementation of current infection control policies and safety measures.

DII.8a Infection control and safety measures for the preparation, dispensing and disposal of pharmaceuticals include but are not limited to:

1) Observation of standard precautions
2) Adequate hand hygiene/hand washing
3) Procedures for preventing exposure to blood borne pathogens
4) Glove, gown and eye shield use while compounding hazardous products and chemotherapeutic substances
5) Use of aseptic technique
6) Appropriate use of particulate and/or bacterial filtration
7) Hood decontamination practices
8) Venting of the laminar flow hood outside the building or use of a Class II Biological Safety Cabinet when compounding cytotoxic drugs
9) Proper disposal of needles used in the preparation of pharmaceuticals done by disposing of needles in a tamper proof, puncture resistant container
10) Proper disposal for hazardous waste products

DII.8b When applicable, the home environment is assessed to evaluate potential safety hazards and to instruct the client and/or those associated with the care of the client about safety precautions. The assessment and client teaching is documented in the client's record.

DII.8c Disposal of outdated drugs, controlled substances or hazardous wastes is documented and conforms to state and federal requirements.

1) Controlled substances are returned to the Drug Enforcement Administration if required. Documentation of the disposal of controlled substances on site is witnessed by two individuals and includes the amount and type of the drug.
2) Material Safety Data Information is kept in the pharmacy and identifies procedures for disposal of hazardous products
3) Clients are instructed regarding the proper disposal of hazardous products in the home
4) Records are maintained, as required

DII.8d When clients and caregivers prepare sterile preparations in the home, they are instructed verbally and in writing regarding safeguards against microbial contamination, including, but not limited to the following:

1) Instructions regarding the preparation of the sterile solution
2) Storage methods
3) Duration and stability of the prepared solution

LEGEND:

D - DOCUMENTATION
I - INTERVIEW
O - OBSERVATION
S - SURVEY

DII.8 cont'd

D: Written infection control and safety policies for equipment/delivery service are available. (DII.8e)

I & O: Staff demonstrate an understanding of infection control procedures and policies. (DII.8f)

D: Policies specify elements 1 – 5 of DII.8f. (DII.8f)

D: Policies specify maintenance, testing, and repair specifications for each type of equipment. (DII.8f)

I & O: Equipment is maintained, tested, and repaired according to manufacturer's recommendations. (DII.8f)

D & O: Review of records and observation of practice confirms adherence to organizational policies and that activities are conducted on a routine basis. (DII.8f)

DII.8e Infection control and safety control policies are established and implemented for the equipment/delivery service, including:

1) Maintenance, testing and repair of equipment according to manufacturer's guidelines
2) Cleaning and storage of reusable equipment between usage
3) Inspection of equipment prior to delivery.

DII.8f The Pharmacy Program that prepares compounded sterile products conducts the following activities on a routine basis:

1) Routine disinfection and quality testing of direct compounding environment
2) Visual confirmation of personnel processes regarding gowning, and other infection control/safety measures
3) Review of orders and packages of ingredients to assure correct identity and amounts of ingredients
4) Visual inspection of compounding sterile products
5) Media-fill test procedure performed at least annually for each person

LEGEND:

D - DOCUMENTATION
I - INTERVIEW
O - OBSERVATION
S - SURVEY

DII.9

D: Documentation validates that the complaint process includes elements 1-9. (DII.9a)

D: Review of complaint log validates that complaints have been responded to consistent with the organization's policy and process. (DII.9a)

DII.9	Client complaints and concerns are responded to and resolved in a timely manner.

DII.9a The complaint process includes:

1) Designation of the individual(s) responsible for responding to the complaint
2) Procedures for responding to complaints
3) Time frame for responding to complaints
4) Assurance that corrective action is taken as appropriate
5) Assurance that client and family rights are protected
6) Follow-up activities
7) Resolution of the complaint
8) Complainant is informed of the outcome
9) Trending of justified complaints

DIII.

THE PHARMACY ORGANIZATION HAS ADEQUATE HUMAN, FINANCIAL, AND PHYSICAL RESOURCES, WHICH ARE EFFECTIVELY ORGANIZED TO ACCOMPLISH ITS STATED MISSION

LEGEND:

D - DOCUMENTATION
I - INTERVIEW
O - OBSERVATION
S - SURVEY

DIII.1

D: Staffing assignments are available. (DIII.1a)

I: Mechanisms for evaluating workload demands are described. (DIII.1a)

I: Mechanisms for employee selection are described. (DIII.1b)

D: Documentation of required elements 1-10 validates compliance and inclusion in the personnel files, health files, or the administration files. (DII.1b)

D: Records include diplomas/transcripts, current licenses and continuing education attendance (if required) for all clinical/professional staff. (DIII.1b.3, 4, 5)

D: Documentation of certification or adequate training is available for Pharmacy Technicians and Delivery personnel identifying training provided for all tasks performed by the technician and the Driving personnel. (DIII.1b.6, 8)

I: Delivery and equipment service personnel selection process is described, including driving record checks, and compliance with relevant motor carrier safety regulations. (DIII.1b.7)

I: Mechanisms for assessing and updating clinical competencies/skills are described. (DIII.1c)

D: Documentation of clinical competency/skill assessment at time of hire and annually thereafter is available. (DIII.1c)

D: Documentation of clinical competency assessment including elements 1-5 at time of hire and annually thereafter is available. (DIII.1d)

I; Mechanism for assessing clinical competency is described by manger and pharmacy personnel. (DIII.1d)

DIII.1	The Pharmacy organization has adequate and appropriate human resources to meet workload demands.

DIII.1a Staffing guidelines are developed and implemented to adequately meet workload demand.

DIII.1b Qualified personnel are recruited and retained. Documentation is found in the personnel files, health files or administration files of the following:

1) Budgets allocate sufficient funds to ensure staffing at all levels and are maintained to adequately meet workload demands
2) Positions, new and vacant, are filled on a timely basis to sustain organizational performance goals
3) Clinical staff show evidence of graduation from colleges approved or accredited by their respective professional organization
4) Clinical staff maintain and show evidence of current licensure
5) Clinical staff show evidence of continuing education when required
6) Pharmacy technicians show evidence of certification, or have evidence of adequate training, for all tasks performed in conformance with applicable laws
7) Delivery personnel, when utilized, have a clean driving record and maintain a current driver's license
8) Delivery personnel, when utilized, show evidence of adequate training for all tasks performed
9) Professional & technical personnel show evidence that professional skills are assessed and updated
10) Compounding personnel show evidence of skills, training, and competency testing to perform and document compounding duties.

DIII.1c Clinical competency evaluations are performed to assess employee basic skill levels for all staff providing client care/services:

1) At time of hire
2) Annually, thereafter

DIII.1d Clinical competency evaluations of pharmacy personnel who use laminar flow hoods and/or Class II Biological safety cabinets are conducted at time of hire and annually thereafter and include at a minimum:

1) Written test to verify employee's understanding of the concepts of aseptic technique
2) Observation of employee's aseptic technique
3) Sterility validation testing for all employees who make sterile products
4) Observation of cleaning, testing and calibration of infusion equipment
5) Observation of cleaning, testing and calibration of compounding equipment

LEGEND:

D - DOCUMENTATION
I - INTERVIEW
O - OBSERVATION
S - SURVEY

DIII.1 cont'd

D: An orientation plan is available and includes elements 1-5. (DIII.1e)

D & I: There is an appropriate supervision plan for all levels of staff and each employee. (DIII.1f)

D: Records show documentation of state/organizational required in-service attendance by pharmacists. (DIII.1g)

Note: In-services may be provided by the organization or other approved entities.

D: Records show documentation of organization's provision of annual in-service program and pharmacist's attendance at the in-service. (DIII.1h)

DIII.1e The orientation plan addresses at a minimum:

1) Mission statement
2) Organizational Chart
3) Lines of authority and responsibility
4) Job related responsibilities (job description)
5) Human Resources policies/conditions of employment

DIII.1f There is adequate supervision of all pharmacy personnel.

1) Professional Pharmacy services are provided by or under the direction and supervision of a qualified Pharmacist.
2) Staffing ratios of pharmacists to pharmacy technicians are in compliance with state regulations.

DIII.1g Pharmacists show evidence of participation in formal in-service programs required by state regulation and organization policy.

DIII.1h The organization provides a minimum of one medication safety in-service annually.

LEGEND:

D - DOCUMENTATION
I - INTERVIEW
O - OBSERVATION
S - SURVEY

DIII.2

D: Contracts for Pharmacy services contain all elements in CIII.2a-b, DIII.2a and DIII.2b. (DIII.2b)

D: Contracts for Delivery services contain all elements in CIII.2a-b, DIII.2a and DIII.2c. (DIII.2c)

I: Pharmacy Director describes mechanism for assuring compliance with responsibilities. (DIII.2)

DIII.2	Formal written contracts and agreements with other organizations and/or individuals for the provision of pharmacy products and services to pharmacy organization clients detail specific responsibilities of the parties involved.

DIII.2a Formal written contracts and agreements with other organizations and/or individuals for provision of pharmacy services includes specific responsibilities as defined in CIII.2a-b and, in addition, the following specific responsibilities:

1) Which organization has the authority to accept and terminate client services
2) Services provided under contract must be in compliance with professional standards
3) The manner, in which products and services will be controlled, coordinated and evaluated
4) Designation of responsibilities for orientation

DIII.2b Pharmacy services when provided under arrangement are in accordance with CHAP Pharmacy Standards and are in compliance with CIII.2a-b, DIII.2a and, in addition, include the provisions for:

1) Who is responsible for teaching the client about pharmaceuticals
2) Assurance that personnel meet the pharmacy program's educational and training requirements
3) Maintenance of current licensure and certification where required
4) On site supervision of pharmacy personnel
5) Hours when pharmaceutical services are available to the client, including arrangements for services during "off hours"
6) Time frames for response to new referrals
7) Responsibilities of contractor and contractee, including:
   (a) Who assesses the need for pharmaceuticals
   (b) Who contacts the pharmacy
   (c) Who obtains the written physician orders
   (d) Who generates drug profiles and to whom they will be made available of those involved with the client's care
   (e) Who maintains records for investigational drugs and controlled substances
   (f) Procedure to follow assuring the availability of drugs and supplies to the clients in their home when not available from the pharmacy
   (g) Mechanisms for evaluating the contracted service

DIII.2c Delivery of products and supplies when provided to clients under arrangement are in compliance with CIII.2 a-b, DIII.2a and, in addition, include the provisions for:

1) Ensuring clean and safe transport of equipment and supplies
2) Timely delivery of products and supplies
3) Setting up equipment in client's homes, where appropriate
4) Adequately trained delivery personnel
5) Client education, where appropriate
6) Appropriate documentation

LEGEND:

D - DOCUMENTATION
I - INTERVIEW
O - OBSERVATION
S - SURVEY

DIII.3

D: Policies pertaining to cash management and contingency planning are available. (DIII.3a)

I: Pharmacy Director describes how the organization manages its cash and cites examples of contingency planning. (DIII.3a)

D&I: Pharmacy Director and/or Financial Manager describe and document the insurance coverage and discuss the rationale for the amounts. (DIII.3b)

D: New Pharmacy product/service plan proposals include specified elements. (DIII.3c)

I: Management team describes examples of recognition of inter-relationship of finance, quality, product and service operations. (DIII.3d)

DIII.3	The Pharmacy Organization/Program has adequate and appropriate financial resources to meet its stated mission.

DIII.3a The organization has a contingency plan and/or policies and procedures to adequately address cash or operating short falls that may impact the products and services it provides.

DIII.3b Insurance coverage is maintained for the loss due to general liability, product liability, professional liability and work related injuries.

DIII.3c New program, product or service planning and development occurs prior to implementation which includes analysis of effectiveness and profitability of the project.

DIII.3d The management team's performance reflects an understanding of the interrelationship of finances, quality, product and service operations and long term viability of the organization.

LEGEND:

D - DOCUMENTATION
I - INTERVIEW
O - OBSERVATION
S - SURVEY

DIII.4

O: Observation of the physical facility validates that elements 1 -7 are in evidence and in conformance with state/federal requirements. (DIII.4a)

D: Written policies specify elements 1-5. (DIII.4b)

O: Work surfaces and equipment are cleaned and disinfected in compliance with pharmacy policy. (DIII.4b)

Note: Compounding environment includes walls and floors. (DIII.4b.2)

D,I&O: Interview, observation and review of reference data validate that professional/community standards of practice are followed. (DIII.4c)

O: Observation validates that sterile and non-sterile preparation areas are separate and adequate. (DIII.4d)

D&O: Observation of injectible drug work areas and review of end product testing results validate compliance with the specifications designated in elements 1-3. (DIII.4e)

DIII.4	The Pharmacy organization has adequate and appropriate physical facilities to accomplish its stated mission.

DIII.4a The Pharmacy organization has the necessary space, equipment and supplies for safe preparation, dispensing, storage and delivery of pharmaceuticals in compliance with state and federal requirements, and includes at a minimum:

1) Preparation of sterile products for dispensing *is within an ISO Class 5 environment*
2) Hot and cold running water with sink
3) Walls, ceilings and floors made of non-porous cleanable surfaces
4) Accurate balance and measuring devices
5) Adequate ventilation and lighting
6) Disposable hand drying towels
7) Adequate storage facilities
   (a) Parenteral compounding items stored to maintain integrity of aseptic environment
   (b) Adequate refrigerator/freezer capacity to meet storage requirements for all refrigeration-required materials.
   (c) Shelves and storage containers made of washable, non-porous materials, including non-use of corrugated cardboard/styrofoam

DIII.4b The Pharmacy organization maintains adequate and clean compounding areas in compliance with its policies which specify:

1) The adequacy of workspace per state regulations
2) Frequency, types of cleaning agents and procedures of how work surfaces, equipment and compounding environment are cleaned and disinfected
3) Work surfaces are kept free of equipment, supplies, records and other material unrelated to the preparation of a given drug
4) Certification of laminar flow hood per organizational policy and/or state/federal regulation
5) Validation of cleaning and compounding practice including surface sampling, environmental air sampling and end product sterility testing for pyrogens.

DIII.4c Storage of the final pharmaceutical product is in accordance with acceptable professional/community standards of practice which are supported by reference data, including temperature, light and length of time.

DIII.4d Areas for compounding of sterile products are functionally separate from areas for the preparation of non-sterile products and are constructed to minimize opportunities for contamination of products.

DIII.4e There are adequate work areas for the preparation and manipulation of injectable drugs, which includes the following:

1) Methods for inspecting ingredients and final products for the presence of inappropriate particulate matter or signs of deterioration or microbial contamination
2) Use of laminar flow hoods
3) Use of Class II Biological Safety Cabinets for the preparation of cytotoxic drugs

Revised: 3/13/06

LEGEND:

D - DOCUMENTATION
I - INTERVIEW
O - OBSERVATION
S - SURVEY

DIII.4 cont'd

D: Documentation of semi-annual inspections and pre-filter changes as required is available. (DIII.4f)

D: Certification reports from the most current three year period are available. (DIII.4f)

I & O: Pharmacy personnel are knowledgeable of and use appropriate techniques when using a hood or cabinet. (DIII.4g).

I&O: Interviews with staff and observation of practice confirms compliance with policies. (DIII.4h, DIII.4i, DIII.4j)

D: Written policies specify elements 1-5. (DIII.4k)

O: Products are shipped in compliance with the pharmacy's policy. (DIII.4k)

O: Client service areas are private, clean, safe and in compliance with ADA regulations. (DIII.4l)

DIII.4f Laminar Flow Hoods and Class II Biological safety cabinets are inspected at least every six months and certified by an independent agency that they are operating according to specifications. Certification records are retained for a minimum of three years.

DIII.4g Pharmacy personnel using a laminar flow hood or a Class II Biological safety cabinet use proper techniques consistent with professional standards of practice to ensure a continuous aseptic environment during the admixing of sterile pharmaceuticals.

DIII.4h Preparation of injectables from sterile solutions includes the use of filters when removing solutions from ampules.

DIII.4i Injectables prepared from non-sterile powders are:

1) Dissolved in sterile solution for injection
2) Filtered through a 0.2 micron filter.

DIII.4j Respiratory medications prepared from non-sterile powders are prepared in an ISO 5 environment and are:

1) Dissolved in sterile solution
2) Filtered through a 0.2 micron filter
3) Packaged under ISO 5 environment conditions
4) Periodically end product tested

DIII.4k Adequate shipping containers and shipping processes are used in accordance with regulations and manufacturers guidelines to assure drug stability and potency which includes the following:

1) Assurance of stability and potency of the products being shipped
2) Temperature control
3) Non-exposure to light
4) Non-exposure to contaminants
5) Packaging of medications in a tamper evident manner

DIII.4l The organization's physical facilities provide a safe environment for staff and clients and allow for the efficient provision of services.

1) Space and privacy are adequate for the services being provided
2) Physical facilities and resources permit effective and efficient function of the personnel
3) Provisions are made to accommodate clients and staff with disabilities

LEGEND:

D - DOCUMENTATION
I - INTERVIEW
O - OBSERVATION
S - SURVEY

DIII.5

D: External databases are available and used for comparison. (DIII.5a)

D: Benchmark reports are available. (DIII.5b)

Note: Organizations may use internal standards, professional standards of practice guidelines, research findings or professional references to determine benchmarks.

Organizations may use multiple sites, divisions and/or professional reference data to benchmark against.

DIII.5	An effective and efficient management information system is utilized to ensure accountability at all levels of the organization.

DIII.5a When available, the organization uses external databases that provide information relevant to the organization's products and services and creates a basis for comparative analysis.

DIII.5b The organization participates in a benchmarking system.

1) Benchmark data are consistent with organizationally defined goals and objectives
2) Benchmark collected data, when available, are measured against data from other organizations

DIV.

THE PHARMACY ORGANIZATION IS POSITIONED FOR LONG TERM VIABILITY

LEGEND:

D - DOCUMENTATION
I - INTERVIEW
O - OBSERVATION
S - SURVEY

DIV.1

D: The pharmacy operational plan is available. (DIV.1a)

D: Governing Body meeting minutes document approval of the initial pharmacy operational plan and changes. (DIV.1b)

DIV.1	Operational planning reflects the Pharmacy's mission.

DIV.1a The planning process focuses on performance expectations and is consistent with organizational needs.

DIV.1b The written plan is developed, and the initial plan and changes are approved by the governing body.

LEGEND:

D - DOCUMENTATION
I - INTERVIEW
O - OBSERVATION
S - SURVEY

DIV.2

D: An annual evaluation of the pharmacy organization's program and operations is conducted. (DIV.2)

I: Management describes the annual evaluation process and the way it is used for future planning for the organization. (DIV.2a)

I: Management personnel describe how the complexity of the organization relates to data collection and utilization. (CIV.2b)

D & I: Evidence exists that product and service pricing is routinely evaluated. (DIV.2c)

D: The interrelationship between the pharmacy program evaluation and the overall organizational evaluation is evident when the pharmacy is part of a larger organization. (DIV.2d)

DIV.2	An annual systematic evaluation of major aspects of the Pharmacy Organization's program and operations provides the basis for future planning.

DIV.2a	Mechanisms are established in writing for the collection, dissemination and use of information for the purpose of management, quality improvement, planning and future evaluation purposes.
DIV.2b	Data appropriate to the complexity and scope of the Pharmacy organization is collected and monitored.
DIV.2c	Pricing of products and services is routinely evaluated.
DIV.2d	Results of the Pharmacy organization's evaluation findings are integrated into the corporate organization's report, if applicable.

LEGEND:

D - DOCUMENTATION
I - INTERVIEW
O - OBSERVATION
S - SURVEY

DIV.3

O: Innovations have been developed and implemented. (DIV.3)

DIV.3	The Pharmacy Organization management team fosters innovation within the organization and brings strong leadership to industry-related activities.

DIV.3a A common and futuristic vision of the organization is established and sustained.

1) A learning environment for all staff is promoted and supported
2) Staff development is encouraged
3) Governing body members have expertise specific to the enhancement of the organization's mission

DIV.3b An atmosphere of mutual respect permeates the organization throughout.

1) Interaction between staff, administration and governing body is evident and is facilitated

DIV.3c The organization has positioned itself to participate in public forums that shape health care policy and educate consumers.

DIV.3d The organization actively networks with other providers and provider organizations.

PHARMACY

SELF STUDY

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INTRODUCTION TO PHARMACY SELF STUDY

The Community Health Accreditation Program, Inc. (CHAP) accreditation process is comprised of five steps:

1) Submission of an application and application fee
2) Submission of a signed contract accompanied by a pre-determined initial fee
3) Submission of a completed Self- Study
4) Comprehensive Site Visit by a team of professionals, the number of which is determined based on the size of the organization and complexity of services provided.
5) Review of the site visit report and determination of accreditation status by the CHAP Board of Review

The Self-Study process is completed by the organization seeking CHAP Accreditation:

1) Prior to the initial site visit
2) Prior to the first visit of a new accreditation cycle

What is the Self-Study?

The Pharmacy Self-Study is a dynamic tool, used by pharmacy programs/services seeking CHAP accreditation that assists the organization in preparing for the on-site accreditation visit. The process involves a comprehensive internal self-assessment of the organization's:

- Structure and Function
- Quality of Services and Products provided
- Resources: Human, Financial and Physical
- Long Term Viability

The Self-Study, 2004 Edition, has been revised to:

- Reflect the flow and content of Pharmacy Standards, 2004 Edition
- Apply to all pharmacy services and programs accredited by CHAP
- Promote the involvement of staff in the preparatory process to achieve accreditation by CHAP
- Facilitate ease of use of the document by all levels of staff
- Infuse a new sense of organizational vitality, unity and sense of pride in completing a "job well done"
- Assist the organization in determining a sense of readiness for the actual on-site visit

It is also anticipated that this new self-study format will:

- Simplify the preparatory process for all organizations seeking CHAP accreditation
- Eliminate duplication and redundancy when used in combination with the CORE 2004 Edition Self-Study
- Identify internal challenges and strategic issues to be addressed prior to the on-site CHAP Accreditation Site Visit

How does CHAP use the Self-Study?

On receipt of the completed self-study, the CHAP office staff completes an internal audit of the document for completeness and the inclusion of required attachments. The designated Site Visitor(s), assigned to conduct the actual site visit also receives a copy of the Self-Study document. The site visitor(s) studies and analyzes the document and attachments submitted in order to construct a plan that will facilitate the efficiency and effectiveness of all facets of the accreditation site visit process.

Additionally, after the completion of the on-site visit and development of the Site Visit Report, the Self-Study is available with the packet of information that is reviewed and acted upon by the Board of Review in making the final accreditation decision.

Suggestions for the Completion of the Self-Study

CHAP recommends that a coordinating committee be appointed, comprised of representatives from each of the organization's programs and/or departments. Selection of a chairperson, who assumes oversight responsibilities for the group, will assure adherence to established time frames and keep the committee focused on achieving a positive accreditation outcome. CHAP recommends that Sections I, II, III, and IV of the CORE Self-Study be completed prior to completing the companion sections in the Pharmacy Self-Study in order to avoid duplicative responses. CHAP also recommends that the CORE and Pharmacy Standards of Excellence and Evidence Guidelines be utilized with the self-study as the organization assesses itself for compliance with the CHAP Standards.

Reaching group consensus on implementing a working agenda

- Strategies for completion of the document
- Assignment of responsible parties
- Estimated time frames for completion of various components of the process
- Processes for monitoring specific activities
- Meeting schedules and progress reports
- Projected date for the submission of the completed Self-Study document
- Retrenchment as necessary and indicated

CHAP Accreditation staff are available and may be contacted by telephone or email for clarification of standards and questions as they arise during completion of the Self-Study.

Directions for Completion of the Pharmacy Self-Study Document

The CORE Standards and Self Study, 2004 Edition, are used in concert with the Pharmacy Standards and Self-Study, 2004 Edition. Complete the following documents of the Self-Study:

1) Contact Information Sheet
2) Organizational Data Sheets
3) Organizational Questions
4) Self-Study Spreadsheet

1) Contact Information Sheet

Specify the name and informational data for the person to be contacted regarding the Self-Study and site visit information.

2) Organizational Data Sheets

Complete for the most current fiscal or calendar year period. These data are used by CHAP staff to assure appropriate staffing for the site visit and to prepare for the site visit.

3) Organizational Questions

Be specific in your responses to the questions. These questions are intended to provide a snap-shot of the organization and its compliance with the underlying principles in the CHAP standards. Site visitors will verify the information at the time of the site visit.

4) Self-Study Spreadsheet

A spreadsheet format has been used to develop the revised self-study, affording the option of employing a computerized response. The written content follows that of the Pharmacy Standards of Excellence, 2004Edition, and details CHAP's four underlying principles:

1) Structure and Function
2) Quality of Services and Products
3) Adequate Resources: Human, Financial and Physical
4) Long Term Viability

The eight (8) column format is defined as follows from left to right:

Column 1 CHAP Standards Alpha-numeric identifiers

Column 2 A description of the Underlying Principles and a duplication of the CHAP Pharmacy:

- Standard Statements
- Criterion Statements
- Elements of the Criterion (numeric identifier i.e., 1)
- Sub elements of a Criterion (identified by use of an alpha letter, i.e., a)

Note: In rare instances, further enhancement of a sub-element is indicated by a (-) sign.

Columns 3&4 Identification of documents/information/activities that are either "In Place" or "Not In Place"

- 3 = "Yes" If in place, check appropriate box
- 4 = "No" If not in place, check appropriate box

Column 5 "N/A" - Used to indicate that a Standard, Criterion, Element or Sub-element is not applicable to the organization completing the Self-Study. If N/A, check appropriate box

Column 6 "A/R" Indicates those standards/criterion which must have a substantiating document submitted as an attachment to the Self-Study. That designation will be included on the Self-Study by CHAP prior to being sent to your organization

Column 7 "A/O" – Attachment Optional. An attachment that may be designated by CHAP or the organization seeking accreditation

Column 8 Comment space for notations or points of clarification by the organization seeking accreditation by CHAP

Submission of Self-Study:

Send the completed self-study with the required attachments to the CHAP Site Visit Coordinator, 39 Broadway, Suite 710, New York, NY 10006. Refer to the original CHAP contract letter for specific number of self-studies required to be submitted.

Pharmacy Self Study

(Contact Information)

For: _____
Name of Organization

Location: _____

_____

Contact: _____

Telephone: _____

E-mail: _____

Submission Date: _____

Note: This should be the first page of your Self Study.

Mail to: **Site Visitor Coordinator**
CHAP, Inc.
39 Broadway, Suite 710
New York, NY 10006

ORGANIZATIONAL DATA SHEET
PHARMACY

Administrative Profile
(Only include positions not included in CORE)

Current Staffing:

	*FTE Positions Budgeted**	*Current FTEs**	*Vacant Positions*	*Contract Staff*
Executive Staff:				
Supervisory Staff:				
Support Staff (office/clerical):				
Sales Representatives Staff:				
Clinical Staff (RPh//RN/RT):				
Pharmacy Technician: :				
Other Technicians:				
Delivery Personnel:				
Other:				

* FTE = Full time equivalent (40 hour week = 2,080 hours per year)

ORGANIZATIONAL DATA SHEET (cont'd.)
PHARMACY

Employee Turnover Rates:

Turnover rates (past fiscal year)	**Pharmacy Staff**	
Positions	*# of Individuals*	*Percent (%)*
Administrative/management staff		
Supervisory staff		
Support Staff (Office/Clerical)		
Sales Representatives		
Clinical Staff (RPh/RN/RT)		
Pharmacy Technicians		
Other Technicians		
Delivery Personnel		
Other (specify)		
Total		

ORGANIZATIONAL DATA SHEET (cont'd.)
PHARMACY

Revenue/Expense:

Total annual revenue: $ _____

Total annual expense: $ _____

Insurance Coverage Maintained:

General liability: $ _____ Malpractice: $ _____

Directors & officers liability $ _____ Other $ _____

Products/Services Provided: *(√ Check all that apply)*

	Open Door Pharmacy		Compounding of Non-Sterile Products		On-Site Delivery
	Mail Order Pharmacy		Compounding of Sterile Products		Mailed Delivery
	Infusion Pharmacy		IV Chemotherapy Drugs		Supplies for Infusion
	Long Term Care Pharmacy		Parenteral/Enteral Nutrition		IV Pumps
	Specialty Pharmacy (*Specify Type)*		IV Hydration Therapy		IV Poles
			IV Antibiotics		Other
			Blood Products		

ORGANIZATIONAL DATA SHEET (cont'd.)
PHARMACY

Operating Sites/Locations:

Operating Sites & Locations	**Functions Provided at Each Site/Location √ all applicable**					
List Corporate/Parent Site First. List all Other Sites/Locations/Hours of Operation & Distance from Corporate/Parent Location, & Check all Applicable Functions for Each Site.	Compounding Non-Sterile Products	Compounding Sterile Products	Open Door Pharmacy Services	Mail-Order Pharmacy Services	On Site Delivery Services	Infusion Pharmacy Services

Specify other functions performed which are not listed:

ORGANIZATIONAL DATA SHEET (cont'd.)
PHARMACY

Service Data:

Dates of last fiscal year: _____

Total number unduplicated clients last fiscal year: _____

Total number prescriptions filled last fiscal year: _____

No. of Prescriptions filled per week day: _____

No. of Prescriptions filled per weekend day: _____

No. of on-site deliveries per day: _____

Types of supplies provided: _____

Volume of supplies provided per month: _____

Size of Service Area (i.e., sq. miles): _____

No. of States in Service Area: _____

Names of States in Service Area: _____

No. of Operational Sites/Locations: _____

No. of unduplicated clients per therapy per year:

_____Anti-infective _____TPN _____Inotropic

_____ Chelation _____Chemotherapeutic

_____Steroid _____Hydration

_____Cath Care _____Biotech

ORGANIZATIONAL QUESTIONS

D I. STRUCTURE & FUNCTION OF THE PHARMACY ORGANIZATION

1. How is the pharmacy organization/program structured for administration? Explain how the role of the Pharmacy Program Director is implemented and how the Director fulfills the responsibilities for all professional services.

2. What is the composition of the Pharmacy organization's professional advisory committee? How are the members appointed?

Describe some relevant recommendations and/or outcomes resulting from professional advisory group meetings/activities this past year.

3. Have ethical issues been identified within the past two years? How have they been handled within the organization? Cite an example.

D II. QUALITY OF SERVICES & PRODUCTS PROVIDED

1. How are the necessary services made available to clients at all times (24 hours a day, 7 days per week)? What is the plan for on-call coverage after hours, weekends and holidays?

2. What mechanisms are in place to assure coordination of care with clients, client representatives and other health care professionals?

3. What is the process for assuring client identification prior to dispensing?

4. Describe the Pharmacy Program performance improvement plan. Describe how the findings from the monitoring resulted in identification of problems and improvement in performance. Cite two examples of significant changes made as a result of the performance improvement efforts.

D III. ADEQUATE RESOURCES

1. How are the skills and competencies of all staff providing client care/services assessed and assured?

2. How are the clinical competencies of pharmacy personnel using laminar flow hoods and/or Class II Biological safety cabinets assessed and assured?

3. What is the organization doing to assure medication safety? Cite three examples.

4. If the organization compounds sterile products, how is the organization assuring a safe end product?

D IV. LONG TERM VIABILITY

1 How is the Pharmacy Program evaluated annually (by whom, frequency and parameters or criteria used)? If the Pharmacy Program is part of a larger organization, how is the program evaluation integrated into the overall organizational evaluation?

	PHARMACY STANDARDS	IN PLACE					COMMENTS
		YES	NO	N/A	A/R	A/O	
UP I	STRUCTURE & FUNCTION						
DI.1	**A written statement by the Pharmacy Organization identifies the scope of products and services provided to clients.**				X		
DI.1a	The scope of services statement is periodically reviewed, revised and approved by the governing body but no less than every twelve (12) months.						
DI.1b	The pharmacy's scope of services statement is made available upon request to clients, referral sources and other interested parties.						
DI.2	**The Pharmacy Organization has the structure and functional mechanisms necessary to accomplish its stated scope of services.**						
DI.2a	The Pharmacy Organization has the legal authority to operate and is in compliance with local, state and federal regulations.						
	1) State Board of Pharmacy License						
	2) Business License						
	3) DEA Narcotic License						
	4) d/b/a, Trade Name registration, if applicable						
	5) Tax ID number						
	6) Medicare & Medicaid provider numbers, where applicable						
	7) Specific county and state required authority						
DI.2b	The Pharmacy Organization is required to prepare and maintain a current written disclosure statement signed by the chief executive, addressing applicable elements as frequently as required by state regulations but no less frequently than every three years.						
	1) Names and addresses of individuals or corporations having a combined direct or indirect ownership or controlling interest of 5% or more in the organization						
	2) Names and address of subcontractors in which the organization has a direct or indirect ownership of 5% or more						
	3) Names and addresses of individuals, who are related as spouse, parent, child or sibling to individuals described in (1) and (2) above						
	4) Names and addresses of individuals in (1), (2), and (3) above with an ownership or controlling interest in a Medicare or Medicaid facility						
	5) Names and addresses of officers, directors or partners						
	6) The circumstances of any criminal offense conviction involving Medicare/Medicaid programs on the part of any person(s) or organization(s) in (1), (2) or (3) above and/or, on the part of any managing employee of the organization						
	7) The dates of any changes in ownership or control during the previous twelve (12) months						
	8) The dates of anticipated changes of ownership or control in the next twelve (12) months						

	PHARMACY STANDARDS	IN PLACE					COMMENTS
		YES	NO	N/A	A/R	A/O	
DI.2c	An Advisory Committee of professionals is authorized by the governing body to advise the organization on policies and to evaluate the Pharmacy Program.						
	1) Responsibilities of the committee include establishment and annual review of pharmacy policies and participation in the annual evaluation of the Pharmacy program.						
	2) Membership of the committee includes a physician, a pharmacist, a registered nurse and at least one community representative who is not an employee				X		
	3) Committee meeting minutes reflect the committee's fulfillment of its responsibilities						
	4) The Advisory Committee meets at least once annually.						
DI.2d	Systems exist for obtaining and integrating the most current information into the professional practice to be used in planning, evaluation and decision making in all aspects of the program						
DI.3	**Intra-organizational relationships of the Pharmacy Organization are clearly defined in writing.**						
DI.3a	A current organizational chart illustrates the lines of authority and accountability for all administrative, professional, technical, clinical and clerical personnel.				X		
DI.3b	The complexity of the Pharmacy organization's administrative structure is appropriate for efficient delivery of product and service.						
DI.4	**Authority and responsibility for the overall executive management of the Pharmacy Organization is vested in qualified individuals.**						
DI.4a	The Pharmacy Program Director is a graduate of a pharmacy program accredited by the American Council of Pharmaceutical Education or has passed a Foreign Pharmacy Graduate Equivalency Examination given by the National Association of Boards of Pharmacy, is currently licensed as a Pharmacist in the state.				X		*Resume*
DI.4b	A qualified pharmacist with appropriate knowledge, expertise and experience is responsible for the management, direction, coordination and general supervision of all professional services.				X		*Resume*

	PHARMACY STANDARDS	IN PLACE					COMMENTS
		YES	NO	N/A	A/R	A/O	
DI.4c	The Pharmacy Program Director is responsible for the following areas either directly or by clear delegation:				X		*Job Description*
	1) Organizing and directing the Pharmacy program's operations to assure the availability of services and products provided						
	2) Assuring adequate inventory of pharmaceuticals and supplies necessary to compound and dispense prescriptions appropriately, including periodic inspection for outdated products.						
	3) Assuring all equipment utilized in the delivery of the organization's products and services is properly maintained						
	4) Assuring pharmacy services are provided in compliance with applicable laws, regulations, accreditation standards and ethical standards of practice						
	5) Assuring adequate and appropriate staffing, including recruitment, orientation, in-service education and completion of annual performance appraisal						
	6) Coordinating with other program areas and managers as appropriate, consistent with organizational structure						
	7) Assuring the implementation of a pharmacy performance improvement program including evaluation of the home pharmacy program services						
	8) Assuring Drug Control system consistent with policies and regulatory requirements						
	9) Assuring Drug Dispensing system consistent with policies and regulatory requirements						
	10) Assuring appropriate pharmacy supervision at all times						
	11) Assuring safe and appropriate service policies are developed and implemented						
DI.4d	A qualified individual is designated in writing to act in the absence of the Pharmacy Director.						
DI.5	**Pharmacy policies and procedures reflect an emphasis on quality and ethical practice, relate directly to the scope of the Pharmacy program, and ensure client rights, and ethical standards of business and clinical practice.**						
DI.5a	Organizational literature, policies and procedures accurately reflect the current practice, current professional standards of service and scope of the Pharmacy program.						
DI.5b	Pharmacy Program administrative policies and procedures include:						
	1) Regulatory Compliance				X		
	2) Capital Short-fall Contingency Plan						
	3) Pharmacy Reference Materials						
	4) Annual Evaluation						

	PHARMACY STANDARDS	IN PLACE					COMMENTS
		YES	NO	N/A	A/R	A/O	
DI.5c	Pharmacy Program operational policies and procedures covering the scope of services provided are developed and include at a minimum:						
	1) Storage of final pharmaceutical products						
	2) First dose new drug administration						
	3) Handling investigational drugs						
	4) Client/caregiver instruction				X		
	5) Timely assessment of client eligibility and provision of service						
	6) Notification of referral source if client does not meet admission criteria						
	7) Delivery of services/products, as applicable						
	8) Contents, dispensing and maintenance of infusion emergency kits						
	9) Acquisition, storage, disposition & dispensing of controlled substances				X		
	10) Selection, maintenance, use & control of infusion control devices for drug administration, as applicable						
	11) Client identification confirmation				X		
	12) Availability of latex-free supplies						
	13) Prescription labeling				X		
	14) Materials/Inventory Management						
	15) Equipment cleaning, testing and tracking						
	16) After Hours Coverage				X		
	17) Dispensing Records						
	18) Sterile Admixture Procedures for monitoring for medication errors, surface testing, environmental air sampling and product sterility				X		
	19) Preparation of injectables from sterile solutions				X		
	20) Preparation of injectables from non-sterile powders				X		
	21) Preparation of respiratory drugs from non-sterile powders				X		
	22) Clinical competency testing				X		
	23) Competency testing of sterile product preparation				X		
	24) Medication Error				X		
	25) Recall						
DI.5d	Clinical policies and procedures consistent with professional standards of practice are developed and include at a minimum the following:						
	1) Client Assessment				X		
	2) Medication Assessment						
	3) Drug Profile Review						
	4) Care Planning, as appropriate						
	5) Development of a comprehensive care plan						
	6) Clinical monitoring						

	PHARMACY STANDARDS	IN PLACE					COMMENTS
		YES	NO	N/A	A/R	A/O	
DI.5e	Quality Improvement policies and procedures consistent with professional practice and regulatory mandates are developed and include at a minimum:						
	1) Performance Improvement Plan				X		
	2) Structure and routine maintenance of compounding areas						
	3) Maintenance of Laminar Flow Hood						
	4) Infection control, safety for preparation, dispensing, disposal of pharmaceuticals				X		
DI.5f	Policies identify when a physician or other qualified professional is required to be present for the administration of the first dose of a new drug to detect, monitor and respond to adverse drug reactions.						
DI.6	**The Pharmacy Organization's business and clinical activities are conducted according to ethical standards.**						
DI.6a	A designated and qualified group of professionals/individuals address ethical issues relating to the business and clinical practices of the Pharmacy Organization. The issues include but are not limited to:				X		
	1) Care delivery issues						
	2) Product and service related issues						
	3) Billing and collecting issues						
	4) Medical necessity authorization issues						
	5) Statistical data trending and tracking issues						
DI.6b	Staff are knowledgeable about and carry out their responsibilities for providing products and services in accordance with reimbursement and regulatory guidelines.						
DI.7	**The Pharmacy Organization contributes to the development and expansion of knowledge in Pharmacy practice, as appropriate.**						
DI.7a	A Pharmacy Organization participating in research or investigative studies ensures that clients are fully informed and provide written consent.						
DI.7b	Arrangements for student education experiences are formalized in written contracts or agreements that specify the responsibilities of the Pharmacy organization and the educational institution.						
DI.7c	The Pharmacy organization demonstrates a positive attitude regarding research initiatives and considers requests for research in the area of pharmaceutical practice as appropriate.						
DI.7d	The Pharmacy organization encourages the publication of significant outcomes related to the management and practice of pharmacy.						

	PHARMACY STANDARDS	IN PLACE					COMMENTS
		YES	NO	N/A	A/R	A/O	
UP II	QUALITY OF SERVICES						
DII.1	**The Scope of Services drives the activities of the Pharmacy Organization and ensures public disclosure, client rights, and ethical standards of business and clinical practice.**						
DII.1a	The written public disclosure policy makes the Annual Report for Corporations, if applicable, available to the public on request.				X		
DII.1b	A written Client Bill of Rights statement or other written admission documents are provided to the client or the client's representative at the start of care or at the time of initiation of care and include the right to be fully informed of:				X		
	1) Services and products being provided						
	2) Organization's ownership and control						
	3) Names and qualifications of individuals providing products and services						
	And the right to:						
	4) Participate in one's own care						
	5) Continuity of products and services						
	6) Education about the products and services to be provided						
	7) Refuse part or all of the products and services to be provided						
	8) Receive products and services in a timely manner and in accordance with organizational policy						
	9) Be referred to another organization						
	10) Be free from abuse or exploitation of any kind						
	11) Receive information, both verbal and written, in an understandable format.						
DII.1c	The Client Bill of Rights is signed by the client or a representative of the client and made a permanent part of the client's record.						
DII.1d	For clients receiving open door pharmacy services, the Client Bill of Rights is posted in a public area accessible to those clients.						
DII.1e	The Pharmacy organization's products and services are provided in accordance with the organization's scope of services.						
	1) Statistical reports confirm that products and services are provided consistent with the Pharmacy organization's scope of services.				X		
	2) Staff at all levels are knowledgeable about and support the Pharmacy organization's mission and scope of services.						

	PHARMACY STANDARDS	IN PLACE					COMMENTS
		YES	NO	N/A	A/R	A/O	
DII.2	**Pharmacy services are provided in accordance with organizational policies and procedures, to clients in their place of residence, and may include dispensing at the pharmacy site, transported delivery to home/client site or mailed delivery.**						
DII.2a	Pharmacy services include but are not limited to:						
	1) Interpretation and evaluation of the prescription order						
	2) Drug product selection, compounding, dispensing, storage						
	3) Distribution of drugs and devices						
	4) Advising the prescriber and other health care professionals, the client and/or caregiver as to therapeutic actions, utilization and possible adverse reactions and interactions in order to encourage a positive client outcome.						
DII.2b	Pharmacy services are provided by or under the direction and supervision of a qualified pharmacist.						
	1) Professional pharmacy service is provided by a registered pharmacist and include:				X		*Job Description*
	(a) Overseeing the drug control system including:						
	1) Receipt of prescription drugs and prescription orders						
	2) Storage of medications						
	3) Packaging of medications						
	4) Preparation and dispensing of prescriptions						
	5) Labeling						
	6) Preparation of prescriptions for delivery						
	(b) Instruction/counseling clients and caregivers regarding specific drug therapy including possible adverse reactions and/or interactions						
	(c) Providing information regarding the safe and appropriate use of medications to other health care professional						
	(d) Identifying appropriate outcomes of drug therapy						
	(e) Consulting on drug therapy and coordinating with other health care professionals						
	(f) Monitoring and documenting ongoing drug therapy including the assessment of:						
	1) The therapeutic appropriateness of the choice of drug(s)						
	2) Therapeutic duplication in the client's drug routine						
	3) Appropriateness of the dose, frequency and route of administration						
	4) Adherence to drug regimen						
	5) Potential drug, food or diagnostic test interactions of disease limitations to drug use						
	6) Laboratory or clinical monitoring methods to detect drug effectiveness, side effects, toxicity or adverse effects						
	7) Preparing and maintaining clinical records						
	(g) Prescribing activities consistent with state/federal regulations.						

	PHARMACY STANDARDS	IN PLACE					COMMENTS
		YES	NO	N/A	A/R	A/O	
	2) Pharmacy technical services are provided by pharmacy technicians who have been trained for all tasks performed in compliance with state law, job description and organizational policy.				X		*Job Description*
DII.2c	The Pharmacy Program provides pharmaceutical care, related supplies and equipment to clients.						
DII.2d	Delivery services are provided directly or by arrangement in compliance with laws and regulations and include:				X		*Job Description*
	1) Safe and clean transport of pharmaceuticals and supplies to and from client homes/designated sites						
	2) Timely delivery of pharmaceuticals and supplies						
	3) Record keeping						
	4) Setting up equipment in client homes, if applicable						
DII.2e	The organization has a process in place for assuring the availability of drug and supplies to clients in their designated sites not available from the organization.				X		
DII.2f	The organization has a process in place for assuring the provision of infusion devices to clients in their homes/designated sites when not available from the organization.				X		
DII.3	**Clinical services and products are accessible and available to clients on an emergency basis 24 hours a day, 7 days a week.**						
DII.3a	The Pharmacy Organization is accessible and responsive to the needs of Clients during normal work hours and after hours which includes:						
	1) Timely telephone response						
	2) Timely on-site response, if indicated						
	3) Product and service delivery prior to scheduled use						
DII.3b	There is a plan for on-call coverage for after hours, weekends and holidays.				X		
DII.3c	Clients are informed of the process for accessing service during normal work hours and after hours.				X		
DII.3d	Written contingency plans delineate protocols for prioritizing delivery of product and services to clients including:						
	1) Disaster preparedness						
	2) Inclement weather events						
	3) Unexpected critical staffing deficits						
DII.4	**The Pharmacy Organization admits clients whose service needs can be met and ensures continuity of care/service through coordination of client services.**						
DII.4a	Clients are admitted to service and continued on service, based on the reasonable expectation that their needs can adequately and safely be met by the program.						

	PHARMACY STANDARDS	IN PLACE					COMMENTS
		YES	NO	N/A	A/R	A/O	
DII.4b	A pharmacist assumes responsibility for planning, implementing therapy, evaluating the outcomes of therapy provided as applicable and documenting in the client record.						
DII.4c	Care is coordinated for each client by the pharmacist and includes at a minimum:						
	1) Periodic verbal, telephone or electronic communication with other professionals involved in the care of the client						
	2) Timely documentation of the coordination of care activities						
	3) Involvement of the client/client representative when indicated						
DII.4d	For other than open door pharmacies, care coordination includes elements 1-3 of DII.4c plus the following additional components:						
	1) Initial assessment of the client, family and, if applicable, the home environment						
	2) Development of a plan of care						
	3) Determination of expected outcomes						
	4) Appropriate referral and follow up						
	5) Implementation of the care plan						
	6) Ongoing evaluation						
	7) Plan of termination of care						
DII.4e	The pharmacist works collaboratively with other health care professionals to assure coordination of care.						
	1) The client drug profile information is available to professionals participating in the care of the client:						
	a) at a minimum, during operating hours for all pharmacies						
	b) at all times, including after hours for infusion pharmacies						
	2) The delivery of medications, equipment, and supplies is coordinated with other professionals involved with the care of the client to ensure that proper products and supplies are available when needed.						
DII.5	**The Pharmacy Organization defines the plan of care process, including assessments, physician oversight, dispensing and client training.**						
DII.5a	An initial client assessment is made by the pharmacist prior to dispensing which includes at a minimum:				X		
	1) Name, address, telephone number, gender, age/date of birth of client						
	2) Allergies/sensitivities of client						
	3) Medication Order						
	4) Physician name, telephone number						

	PHARMACY STANDARDS	IN PLACE					COMMENTS
		YES	NO	N/A	A/R	A/O	
DII.5b	For infusion and long term care pharmacies, an initial client assessment is made by the pharmacist prior to dispensing which includes elements 1-4 of DII.5a plus the following additional components as appropriate:				X		
	1) Chief Complaint/Medical history/Diagnosis						
	2) Height and weight of client						
	3) Client Infection, Sensitivities obtained as available						
	4) Significant Lab Results						
DII.5c	A medication assessment is made by the pharmacist prior to dispensing which includes at a minimum:				X		
	1) Potential drug interaction						
	2) Potential for poly-pharmacy						
	3) Appropriate dose and frequency						
	4) Appropriate time of administration						
	5) Appropriate route and method of administration						
	6) Appropriate infusion device of administration, if applicable						
DII.5d	Pharmaceuticals are dispensed according to the prescription of a physician or physician designee legally authorized to prescribe in compliance with state regulation:						
	1) Written, verbal or faxed prescriptions are available to the pharmacist before dispensing the medication						
	2) Verbal orders taken from a physician or physician designee are recorded and signed by the pharmacist prior to filling the medication order						
DII.5e	All pharmaceutical products dispensed to clients are appropriately labeled according to state and federal regulations and, at a minimum, include:						
	1) Name, address and telephone number of the pharmacy						
	2) Date the prescription was dispensed						
	3) Expiration date of the medication						
	4) Pharmacy's prescription number						
	5) Client's full name						
	6) Name of the drug, brand, strength, if applicable, and the amount dispensed						
	7) Directions for use						
	8) Prescriber's name						
	9) Other pertinent information or cautionary labels						
	10) Rate, route and method of administration						
	11) For IV mixture drugs, rate of administration and expiration date of the fluid						

	PHARMACY STANDARDS	IN PLACE					COMMENTS
		YES	NO	N/A	A/R	A/O	
DII.5f	A comprehensive plan of care is developed by infusion pharmacies which includes:				X		*1 Sample*
	1) Establishment of Therapy Specific Goals						
	2) Determination of Expected Outcomes						
	3) Determination of Educational Needs						
	4) Establishment of Monitoring Plan						
	5) Determination of Achievement of Goals/Outcomes						
	6) Periodic Review by Prescribing Physician						
DII.5g	Client identification is confirmed prior to dispensing.				X		
DII.5h	For pharmacy infusion services, there are policies and procedures for emergency situations including, ordering of emergency kits with appropriate drugs by the physician and placement of these kits in the client's home, where appropriate.				X		
DII.5i	Drug information and instructional materials for administration are provided to the client or client caregiver at the time of dispensing.						
DII.5j	Client training/education in self-administration is provided upon initiation of therapy, as applicable						
DII.6	**Client records are maintained for each client and are utilized as a tool for coordination of services, as legal documentation of products and services provided and as a basis for billing and reimbursement procedures.**						
DII.6a	Adequate and appropriate pharmacy records are maintained						
	1) Drug profiles are maintained for all clients and include the following information:						
	(a) Name, gender, birth date and weight (when appropriate)						
	(b) Address and client identification						
	(c) Allergies or sensitivities						
	(d) Diagnosis						
	(e) Current drug regimen						
	(f) Dosages						
	(g) Relevant clinical information regarding drug therapy						
	(h) Physician's name						

	PHARMACY STANDARDS	IN PLACE YES	NO	N/A	A/R	A/O	COMMENTS
	2) Dispensing records are maintained for pharmaceuticals which include:						
	(a) Client's identification, name and address						
	(b) Name of medication						
	(c) Strength and dosage form						
	(d) Quantity dispensed						
	(e) Physician's name						
	(f) Dispensing pharmacist/technician identification						
	(g) Prescription number						
	(h) Date dispensed						
	(i) Directions for use						
	(j) Expiration date						
	(k) Number of refills authorized						
	3) Dispensing records for other than open door pharmacies are maintained for pharmaceuticals which include elements a-k of DII.6a2 plus the following:						
	(a) Lot number(s) of drugs						
	(b) Date of the addition(s) to intravenous admixture drugs						
	(c) Special compounding instructions as applicable						
	(d) Documentation of verification procedures						
	4) Controlled substance records are maintained in accordance with state, federal and practice regulations documenting that:						
	(a) A controlled substance inventory is performed in compliance with state or federal regulation.						
	(b) The pharmacist in charge is held accountable for the exact count of Schedule II pharmaceuticals						
	(c) The pharmacist in charge is held accountable for an approximate count of Schedule III, IV, and V pharmaceuticals.						
DII.6b	Automated clinical record systems ensure consistent and ongoing protection of data.						
	1) Written policy describes signature authentication in accordance with individual state law				X		
	2) Safeguards prevent unauthorized access to inputted information						
	3) Individual and protected access codes are assigned to individuals designated to perform data entry						
	4) Automated programs designate and control areas of access by authorized personnel based on a personal identifier and position in the organization						
	5) The computer's internal clock designates date and time of entries						
	6) Automated controls prevent a change in entry, allowing only corrections						
	7) Hardcopies of automated data are retrievable by designated personnel						
	8) A system for validation of inputted data is in place						
	9) An automated system for backup and storage of data is controlled, and the data is stored in a safe environmental place.						

	PHARMACY STANDARDS	IN PLACE					COMMENTS
		YES	NO	N/A	A/R	A/O	
DII.7	**The adequacy, appropriateness, effectiveness and outcomes of products, services and supplies provided are routinely assessed.**						
DII.7a	The Pharmacy Program has a formalized quality improvement program which is designed to:						
	1) Identify desired outcomes						
	2) Identify strategic and at-risk activities						
	3) Establish monitoring parameters for these activities						
	4) Establish minimal standards or criteria to be met						
	5) Describe methods used to improve the quality of service and to achieve the desired outcomes.						
DII.7b	The Pharmacy Program has a written performance improvement plan which includes:				X		
	1) Description of specific monitoring and evaluation activities						
	2) Specification of how results are to be reported and evaluated						
	3) Identification of appropriate follow-up mechanisms when thresholds are exceeded						
	4) Delineation of individual responsibilities for each aspect of the program.						
DII.7c	The Pharmacy Program's performance improvement program includes but is not limited to:						
	1) Monitoring for medication errors						
	2) Monitoring and analysis of the findings from surface testing, environmental air sampling and end product testing that includes sterility and pyrogens.						
DII.7d	Staff orientation and in-service programs integrate a focus on quality.						
DII.7e	The Pharmacy Program's performance improvement plan is integrated into the overall organizational quality improvement plan, as applicable.						

	PHARMACY STANDARDS	IN PLACE					COMMENTS
		YES	NO	N/A	A/R	A/O	
DII.8	**The health and well being of employees and clients is promoted and maintained through education and implementation of current infection control policies and safety measures.**						
DII.8a	Infection control and safety measures for the preparation, dispensing and disposal of pharmaceuticals include but are not limited to:				X		
	1) Observation of standard precautions						
	2) Adequate hand hygiene/hand washing						
	3) Procedures for preventing exposure to blood borne pathogens						
	4) Glove, gown and eye shield use while compounding hazardous products and chemotherapeutic substances						
	5) Use of aseptic technique						
	6) Appropriate use of particulate and/or bacterial filtration						
	7) Hood decontamination practices						
	8) Venting of the laminar flow hood outside the building or use of a Class II Biological Safety Cabinet when compounding cytotoxic drugs						
	9) Proper disposal of needles used in the preparation of pharmaceuticals done by disposing of needles in a tamper proof, puncture resistant container						
	10) Proper disposal for hazardous waste products						
DII.8b	When applicable, the home environment is assessed to evaluate potential safety hazards and to instruct the client and/or those associated with the care of the client about safety precautions. The assessment and client teaching is documented in the client's record.						
DII.8c	Disposal of outdated drugs, controlled substances or hazardous wastes is documented and conforms to state and federal requirements.				X		
	1) Controlled substances are returned to the Drug Enforcement Administration if required. Documentation of the disposal of controlled substances on site is witnessed by two individuals and includes the amount and type of the drug.						
	2) Material Safety Data Information is kept in the pharmacy and identifies procedures for disposal of hazardous products						
	3) Clients are instructed regarding the proper disposal of hazardous products in the home						
	4) Records are maintained, as required						
DII.8d	When clients and caregivers prepare sterile preparations in the home, they are instructed verbally and in writing regarding safeguards against microbial contamination, including, but not limited to the following:				X		
	1) Instructions regarding the preparation of the sterile solution						
	2) Storage methods						
	3) Duration and stability of the prepared solution						

	PHARMACY STANDARDS	IN PLACE					COMMENTS
		YES	NO	N/A	A/R	A/O	
DII.8e	Infection control and safety control policies are established and implemented for the equipment/delivery service, including:				X		
	1) Maintenance, testing and repair of equipment according to manufacturer's guidelines						
	2) Cleaning and storage of reusable equipment between usage						
	3) Inspection of equipment prior to delivery.						
DII.8f	The Pharmacy Program that prepares compounded sterile products conducts the following activities on a routine basis:						
	1) Routine disinfection and quality testing of direct compounding environment						
	2) Visual confirmation of personnel processes regarding gowning, and other infection control/safety measures						
	3) Review of orders and packages of ingredients to assure correct identity and amounts of ingredients						
	4) Visual inspection of compounding sterile products						
	5) Media-fill test procedure performed at least annually for each person						
DII.9	**Client complaints and concerns are responded to and resolved in a timely manner.**						
DII.9a	The complaint process includes:						
	1) Designation of the individual(s) responsible for responding to the complaint						
	2) Procedures for responding to complaints						
	3) Time frame for responding to complaints						
	4) Assurance that corrective action is taken as appropriate						
	5) Assurance that client and family rights are protected						
	6) Follow-up activities						
	7) Resolution of the complaint						
	8) Complainant is informed of the outcome						
	9) Trending of justified complaints						

	PHARMACY STANDARDS	IN PLACE					COMMENTS
		YES	NO	N/A	A/R	A/O	
UP III	ADEQUATE RESOURCES - HUMAN, FINANCIAL & PHYSICAL						
DIII.1	**The Pharmacy organization has adequate and appropriate human resources to meet workload demands.**						
DIII.1a	Staffing guidelines are developed and implemented to adequately meet workload demand.				X		
DIII.1b	Qualified personnel are recruited and retained. Documentation is found in the personnel files, health files or administration files of the following:						
	1) Budgets allocate sufficient funds to ensure staffing at all levels and are maintained to adequately meet workload demands						
	2) Positions, new and vacant, are filled on a timely basis to sustain organizational performance goals						
	3) Clinical staff show evidence of graduation from colleges approved or accredited by their respective professional organization						
	4) Clinical staff maintain and show evidence of current licensure						
	5) Clinical staff show evidence of continuing education when required						
	6) Pharmacy technicians show evidence of certification, or have evidence of adequate training, for all tasks performed in conformance with applicable laws						
	7) Delivery personnel, when utilized, have a clean driving record and maintain a current driver's license						
	8) Delivery personnel, when utilized, show evidence of adequate training for all tasks performed						
	9) Professional & technical personnel show evidence that professional skills are assessed and updated						
	10) Compounding personnel show evidence of skills, training, and competency testing to perform and document compounding duties.						
DIII.1c	Clinical competency evaluations are performed to assess employee basic skill levels for all staff providing client care/services:						
	1) At time of hire						
	2) Annually, thereafter						
DIII.1d	Clinical competency evaluations of pharmacy personnel who use laminar flow hoods and/or Class II Biological safety cabinets are conducted at time of hire and annually thereafter and include at a minimum:						
	1) Written test to verify employee's understanding of the concepts of aseptic technique						
	2) Observation of employee's aseptic technique						
	3) Sterility validation testing for all employees who make sterile products						
	4) Observation of cleaning, testing and calibration of infusion equipment						
	5) Observation of cleaning, testing and calibration of compounding equipment						

	PHARMACY STANDARDS	IN PLACE					COMMENTS
		YES	NO	N/A	A/R	A/O	
DIII.1e	The orientation plan addresses at a minimum:				X		
	1) Mission statement						
	2) Organizational Chart						
	3) Lines of authority and responsibility						
	4) Job related responsibilities (job description)						
	5) Human Resources policies/conditions of employment						
DIII.1f	There is adequate supervision of all pharmacy personnel.						
	1) Professional Pharmacy services are provided by or under the direction and supervision of a qualified Pharmacist.						
	2) Staffing ratios of pharmacists to pharmacy technicians are in compliance with state regulations.						
DIII.1g	Pharmacists show evidence of participation in formal in-service programs required by state regulation and organization policy.						
DIII.1h	The organization provides a minimum of one medication safety in-service annually						
DIII.2	**Formal written contracts and agreements with other organizations and/or individuals for the provision of pharmacy products and services to pharmacy organization clients detail specific responsibilities of the parties involved.**						
DIII.2a	Formal written contracts and agreements with other organizations and/or individuals for provision of pharmacy services includes specific responsibilities as defined in CIII.2a-b and, in addition, the following specific responsibilities:				X		*One Prototype*
	1) Which organization has the authority to accept and terminate client services						
	2) Services provided under contract must be in compliance with professional standards						
	3) The manner, in which products and services will be controlled, coordinated and evaluated						
	4) Designation of responsibilities for orientation						
DIII.2b	Pharmacy services when provided under arrangement are in accordance with CHAP Pharmacy Standards and are in compliance with CIII.2a-b, DIII.2a and, in addition, include the provisions for:				X		*One Prototype*
	1) Who is responsible for teaching the client about pharmaceuticals						
	2) Assurance that personnel meet the pharmacy program's educational and training requirements						
	3) Maintenance of current licensure and certification where required						
	4) On site supervision of pharmacy personnel						
	5) Hours when pharmaceutical services are available to the client, including arrangements for services during "off hours"						
	6) Time frames for response to new referrals						

	PHARMACY STANDARDS	IN PLACE					COMMENTS
		YES	NO	N/A	A/R	A/O	
	7) Responsibilities of contractor and contractee, including:						
	(a) Who assesses the need for pharmaceuticals						
	(b) Who contacts the pharmacy						
	(c) Who obtains the written physician orders						
	(d) Who generates drug profiles and to whom they will be made available of those involved with the client's care						
	(e) Who maintains records for investigational drugs and controlled substances						
	(f) Procedure to follow assuring the availability of drugs and supplies to the clients in their home when not available from the pharmacy						
	(g) Mechanisms for evaluating the contracted service						
DIII.2c	Delivery of products and supplies when provided to clients under arrangement are in compliance with CIII.2 a-b, DIII.2a and, in addition, include the provisions for:				X		*One Prototype*
	1) Ensuring clean and safe transport of equipment and supplies						
	2) Timely delivery of products and supplies						
	3) Setting up equipment in client's homes, where appropriate						
	4) Adequately trained delivery personnel						
	5) Client education, where appropriate						
	6) Appropriate documentation						
DIII.3.	**The Pharmacy Organization/Program has adequate and appropriate financial resources to meet its stated mission.**						
DIII.3a	The organization has a contingency plan and/or policies and procedures to adequately address cash or operating short falls that may impact the products and services it provides.				X		
DIII.3b	Insurance coverage is maintained for the loss due to general liability, product liability, professional liability and work related injuries.						
DIII.3c	New program, product or service planning and development occurs prior to implementation which includes analysis of effectiveness and profitability of the project.						
DIII.3d	The management team's performance reflects an understanding of the interrelationship of finances, quality, product and service operations and long term viability of the organization.						

	PHARMACY STANDARDS	IN PLACE					COMMENTS
		YES	NO	N/A	A/R	A/O	
DIII.4	**The Pharmacy organization has adequate and appropriate physical facilities to accomplish its stated mission.**						
DIII.4a	The Pharmacy organization has the necessary space, equipment and supplies for safe preparation, dispensing, storage and delivery of pharmaceuticals in compliance with state and federal requirements, and includes at a minimum:						
	1) Designated area for preparation of sterile products for dispensing						
	2) Hot and cold running water with sink						
	3) Walls, ceilings and floors made of non-porous cleanable surfaces						
	4) Accurate balance and measuring devices						
	5) Adequate ventilation and lighting						
	6) Disposable hand drying towels						
	7) Adequate storage facilities						
	(a) Parenteral compounding items stored to maintain integrity of aseptic environment						
	(b) Adequate refrigerator/freezer capacity to meet storage requirements for all refrigeration-required materials.						
	(c) Shelves and storage containers made of washable, non-porous materials, including non-use of corrugated cardboard/styrofoam						
DIII.4b	The Pharmacy organization maintains adequate and clean compounding areas in compliance with its policies which specify:				X		
	1) The adequacy of workspace per state regulations						
	2) Frequency, types of cleaning agents and procedures of how work surfaces, equipment and compounding environment are cleaned and disinfected						
	3) Work surfaces are kept free of equipment, supplies, records and other material unrelated to the preparation of a given drug						
	4) Certification of laminar flow hood per organizational policy and/or state/federal regulation						
	5) Validation of cleaning and compounding practice including surface sampling, environmental air sampling and end product sterility testing for pyrogens.						
DIII.4c	Storage of the final pharmaceutical product is in accordance with acceptable professional/community standards of practice which are supported by reference data, including temperature, light and length of time.						
DIII.4d	Areas for compounding of sterile products are functionally separate from areas for the preparation of non-sterile products and are constructed to minimize opportunities for contamination of products.						

	PHARMACY STANDARDS	IN PLACE					COMMENTS
		YES	NO	N/A	A/R	A/O	
DIII.4e	There are adequate work areas for the preparation and manipulation of injectable drugs, which includes the following:						
	1) Methods for inspecting ingredients and final products for the presence of inappropriate particulate matter or signs of deterioration or microbial contamination						
	2) Use of laminar flow hoods						
	3) Use of Class II Biological Safety Cabinets for the preparation of cytotoxic drugs						
DIII.4f	Laminar Flow Hoods and Class II Biological safety cabinets are inspected at least every six months and certified by an independent agency that they are operating according to specifications. Certification records are retained for a minimum of three years.						
DIII.4g	Pharmacy personnel using a laminar flow hood or a Class II Biological safety cabinet use proper techniques consistent with professional standards of practice to ensure a continuous aseptic environment during the admixing of sterile pharmaceuticals.						
DIII.4h	Preparation of injectables from sterile solutions includes the use of filters when removing solutions from ampules.						
DIII.4i	Injectables prepared from non-sterile powders are:						
	1) Dissolved in sterile solution for injection						
	2) Filtered through a 0.2 micron filter.						
DIII.4j	Respiratory medications prepared from non-sterile powders are prepared in an ISO 5 environment and are:						
	1) Dissolved in sterile solution						
	2) Filtered through a 0.2 micron filter						
	3) Packaged under ISO 5 environment conditions						
	4) Periodically end product tested						
DIII.4k	Adequate shipping containers and shipping processes are used in accordance with regulations and manufacturers guidelines to assure drug stability and potency which includes the following:						
	1) Assurance of stability and potency of the products being shipped						
	2) Temperature control						
	3) Non-exposure to light						
	4) Non-exposure to contaminants						
	5) Packaging of medications in a tamper evident manner						
DIII.4l	The organization's physical facilities provide a safe environment for staff and clients and allow for the efficient provision of services.						
	1) Space and privacy are adequate for the services being provided						
	2) Physical facilities and resources permit effective and efficient function of the personnel						
	3) Provisions are made to accommodate clients and staff with disabilities						

	PHARMACY STANDARDS	IN PLACE					COMMENTS
		YES	NO	N/A	A/R	A/O	
DIII.5	**An effective and efficient management information system is utilized to ensure accountability at all levels of the organization.**						
DIII.5a	When available, the organization uses external databases that provide information relevant to the organization's products and services and creates a basis for comparative analysis.						
DIII.5b	The organization participates in a benchmarking system.				X		
	1) Benchmark data are consistent with organizationally defined goals and objectives						
	2) Benchmark collected data, when available, are measured against data from other organizations						

	PHARMACY STANDARDS	IN PLACE					COMMENTS
		YES	NO	N/A	A/R	A/O	
UP IV	LONG TERM VIABILITY						
DIV.1	**Operational planning reflects the Pharmacy's mission.**						
DIV.1a	The planning process focuses on performance expectations and is consistent with organizational needs.						
DIV.1b	The written plan is developed, and the initial plan and changes are approved by the governing body.				X		*If Different From Core*
DIV.2	**An annual systematic evaluation of major aspects of the Pharmacy Organization's program and operations provides the basis for future planning.**				X		*If Different From Core*
DIV.2a	Mechanisms are established in writing for the collection, dissemination and use of information for the purpose of management, quality improvement, planning and future evaluation purposes.						
DIV.2b	Data appropriate to the complexity and scope of the Pharmacy organization is collected and monitored.						
DIV.2c	Pricing of products and services is routinely evaluated.						
DIV.2d	Results of the Pharmacy organization's evaluation findings are integrated into the corporate organization's report, if applicable.						
DIV.3	**The Pharmacy Organization management team fosters innovation within the organization and brings strong leadership to industry-related activities.**						
DIV.3a	A common and futuristic vision of the organization is established and sustained.						
	1) A learning environment for all staff is promoted and supported						
	2) Staff development is encouraged						
	3) Governing body members have expertise specific to the enhancement of the organization's mission						
DIV.3b	An atmosphere of mutual respect permeates the organization throughout.						
	1) Interaction between staff, administration and governing body is evident and is facilitated						
DIV.3c	The organization has positioned itself to participate in public forums that shape health care policy and educate consumers.						
DIV.3d	The organization actively networks with other providers and provider organizations.						

SITE VISIT WORKBOOK

Site Visit Dates: _____ **to** _____

Name of Organization: _____

Address: _____ Telephone: _____

_____ Fax: _____

_____ E-mail: _____

Contact Person: _____

Title: _____

Medicare # _____ Medicaid # _____

Other # _____

Visit Type _____

SITE VISITOR CITATIONS:

Commendations	_____	New Required Actions	_____
Former Required Actions	_____	New Recommendations	_____
Met	_____	Medicare Tags	_____
Continued as RA	_____	Deemed Visit (√)	_____
Continued as Rec	_____	Modified Core (√)	_____

Site Visitor Name	Signature	Initials
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____

EVIDENCE GUIDELINES	CITATION STATEMENTS
D = Documentation S = Survey O = Observation I = Interview **D:** Current Mission statement includes a consumer focus and orientation to quality. (CI.1) **D:** Consumers are defined as individuals, groups and communities. (CI.1) **D:** Governing body minutes document actions taken on the mission: (CI.1b) (a) Review and approval at least every 36 months (b) Revisions and updates as applicable **D:** Legal documents specific to the organization, delineate applicable elements of CI.2b which may include :partnership agreement, articles of incorporation, bylaws, state charter, state licensure, tax license, trade name registration, business license, amendments, medicare certification and special waivers. **D:** *Note: Governing Body may be governmental entity. (CI.2c)* **D&I:** Name, address, credentials and professional/business affiliation of each member is identified. (CI.2d) *Note: Owner/Operator of a business may constitute the governing body. Governmental Boards of Health may be advisory in nature and/or may be elected or appointed officials.* **D&I:** New member orientation is validated in writing. Governing body members describe the orientation experience and articulate key issues affecting the organization. (CI.2e) **I:** Governing body members articulate responsibilities and describe the types of actions taken by the board. (CI.2f) *Note: Selected elements may not apply to owner/operator businesses, i.e., selecting the chief administrator.*	

Cl.1	**Published Mission statement clearly identifies commitment to providing high quality services & products which address consumer needs as a priority**								
Cl.1a	Programs & services reflect organization's written mission								
Cl.1b	Mission statement is reviewed/ revised as indicated//approved by GB at least every 36 months								
Cl.2	**Organization has structure & functional mechanisms to support accomplish stated mission**								
Cl.2a G117, 118 L172, 173	Legal authority to operate & is in compliance with local, state, federal regulations								
Cl.2b G117, 118	Applicable Governance Structure is defined in legal documents specific to the organization								
Cl.2c	An identified governing body:								
G128, 129, G130 L107, 108 L110	1) Assumes full legal authority/ responsibility/accountability for organizational performance								
L109	2) Appoints a qualified administrator								
	3) Designates advisory group membership as applicable								
Cl.2d	The GB is made up of individuals with relevant expertise, business acumen,, and professional relationships specific to the stated mission of the organization.								
Cl.2e	GB members are oriented to the organization & are knowledgeable & responsive to key issues affecting the organization								
Cl.2f L107,8,10	GB carries out responsibilities specific to the organization including								
G130,153 L108	1) Establishing policies consistent with organizational mission								
L108	2) Approving new/revised P&P's as indicated & necessary								
G132	3) Holding management accountable for the fiscal solvency of the organization & adequacy of financial resources								
G132, 147, G148	4) Approving budgets & capital expenditures								
G129 L108	5) Selecting & evaluating the chief administrator								
G246	6) Evaluating organizational performance								
	7) Developing & approving strategic plan								
[illegible]	8) Periodically reviewing legal & business documents, at least every 36 mos.(Articles of Incorporation, By-laws, Legal Agreements)								

EVIDENCE GUIDELINES	CITATION STATEMENTS
D = Documentation S = Survey O = Observation I = Interview	
D: Current signed and dated annual disclosure statements are on file for all governing body members and executive staff. (CI.2g)	
D&I: Governing body members confirm adherence by governing body members to legal documents which may describe notice of scheduled and special meetings, attendance requirements at meetings, appointment of officers, terms of office, committee structure and function, quorum determination. (CI.2h)	
D: Governing body minutes reflect agenda items, discussion, and action taken. (CI.2i) *Note: Closed sessions are to be documented and distributed/filed per organizational policy.*	
D: A current organizational chart is dated and reflects lines of authority and accountability for all personnel. (CI.3a)	
D: Amendments to the organizational chart are documented as applicable, (CI.3b)	
I: Staff members are familiar with the organizational chart and state their individual lines of authority and accountability. (CI.3c)	
D: Current job descriptions are on file for administrative and management positions. (CI.4a, b)	
CEO/Administrator/Management resumes validate experience, knowledge, and qualifications required for the job. (CI.4b) *Note: This standard may pertain to the Chief Health Care Administrator in Public Health Organizations.*	
D: Written policy and procedure defines assignment of administrative responsibilities in the absence of the CEO/Administrator. (CI.4c)	
I: Designated alternate to the CEO/Administrator understands his/her role and describes experiences specific to the alternate role. (CI.4c)	

Cl. 2g 106	Annually, GB members & executive staff provide written disclosure of all professional &/or personal relationships or interests, direct or indirect, that might represent a conflict of interest. Statements are on file in office.									
Cl.2h	The GB complies with organizational by-laws or other legal documents.									
Cl.2i	Accurate, complete & signed minutes are kept of all official meetings of the GB, document actions taken, distributed per policy and retained 5 yrs minimum or per state regulations.									
Cl.3	**Intra-organizational relationships are clearly defined**									
Cl.3a G122, 123	Current organizational chart delineates lines of authority & accountability of all personnel									
Cl.3b	Organizational chart is reviewed and changed as needed									
Cl.3c	Personnel understand & use the organizational structure outlined in the organizational chart.									
Cl.4	**Authority & responsibility for overall administration & management is vested in qualified individuals.**									
Cl.4a	Chief executive/administrator's credentials include appropriate industry experience and knowledge of applicable local, state and federal laws.									
Cl.4b	Qualifications for administrative & management positions are defined in writing & are consistent with scope of responsibility & complexity of the organization. Administrative/ mgmt personnel have equivalent combinations of education/ training/ experience to qualify for assigned responsibilities									
Cl.4c G137	Qualified individual is designated in writing to be administratively responsible in the absence of chief executive/administrator									
Cl.4d L124	Admin. & mgmt. responsibilities are clearly defined & delegated as specified and include:									
G133	1) Organizing & directing the organization's ongoing operations to assure availability and provision of care & services									
	2) Implementing governing body directives and organizational policies & procedures.									

EVIDENCE GUIDELINES	CITATION STATEMENTS
D = Documentation S = Survey O = Observation I = Interview I: CEO/Administrative and Management personnel describe their respective areas of responsibility. (CI.4d) I: Management and advisory/governing body members describe process for development, revision and annual review of policies. (CI.5a) D: Administrative policies and procedures address the areas delineated in CI.5b. D: A written safety program sets the parameters for monitoring environmental conditions and identifying potential hazards/risks in accordance with elements such as biomedical waste management, storage and handling of environmental cleaning supplies, fire safety, preventive maintenance of equipment, reporting of malfunctioning equipment, environmental controls to prevent client or staff accidents and or incidents and safety of clients and employees in the community. (CI.5b)	

G118	3) Complying with applicable laws & regulations									
34	4) Recruiting, employing & retaining qualified personnel to maintain appropriate staffing levels									
G134	5) Ensuring adequate staff education									
G134	6) Completing performance evaluations on subordinate staff in accordance with organizational policy									
	7) Directing/monitoring organizational Performance Improvement activities									
G136	8) Managing operations in accordance with established fiscal parameters									
	9) Planning, developing, implementing, administering & evaluating programs									
	10) Representing the organization to other groups, organizations & the general public									
G135	11) Ensuring the accuracy of public information materials									
G133	12) Informing the GB & staff of current organizational, community & industry trends									
CI.5	**Organizational P&P's reflect an emphasis on quality & ethical practice & relate directly to the mission of the organization**									
CI.5a G153	P&P's are developed, revised & reviewed annually to ensure currency of information .									
CI.5b	Administrative P&P's delineate administrative authority & responsibility for governance, planning, financial control & personnel. Policies include at a minimum:									
L106	1) Written disclosure of conflict of interest									
G119, 120 L106	2) Public disclosure of information									
	3) Responsibilities of ethical issues review group									
	4) Rights & responsibilities of clients									
	5) Internal & external complaint management									
	6) Exposure control plan									
	7) Formal safety program									
	8) Financial policies & procedures									
	9) Research activities/investigational studies as applicable									

EVIDENCE GUIDELINES	CITATION STATEMENTS
D = Documentation S = Survey O = Observation I = Interview D: Operational policies and procedures detail planning, delivery and evaluation of care and include the 16 elements of CI.5c. D: Personnel policies address the 9 elements of CI.5d.	

	framework for planning, delivery & evaluation of care & services provided. Policies include at a minimum:									
	1) Non-discrimination statement addressing admission of clients to service									
G156	2) Defined criteria for acceptance/ non-acceptance of clients									
G153,157	3) Admission, continuation of service & discharge									
G330	4) Standardized assessment process									
	5) Referral to other providers of care/services									
G158, 163, G166, 300	6) Medical orders, verbal orders & physician oversight as applicable									
	7) Emergency service									
	8) After hours service									
G111 ,239, G240, 241	9) Confidentiality of protected health information									
	10) Emergency /disaster preparedness									
	11) Health, safety & security of staff during all hours of work									
	12) Services/products provided directly & under contract									
	13) Standards of practice for all disciplines as applicable									
	14) Standards of operations for all products as applicable									
G121	15) Infection control									
	16) Accepted medical term abbreviations									
CI.5d G141	Personnel policies are developed & revised in response to organizational change & include:									
	1) Conditions of employment									
	2) Respective obligations between employer & employee									
	3) Non-discrimination information									
	4) Grievance procedure									
	5) Employee orientation									
	6) Employer exit interviews									
	7) Maintenance of health reports & protected employee information									
	8) Employee record confiden-tiality & record retention									
	9) Recruitment, retention & per-formance evaluation of staff									
CI.5e G121	A written TB Exposure Control Plan is in compliance with the most current CDC applicable recommendations & requirements for occupational exposure to TB.									

EVIDENCE GUIDELINES	CITATION STATEMENTS
D = Documentation S = Survey O = Observation I = Interview	
D: Written TB Exposure Control Plan includes the elements in CI.5e.	
D: Written policy and procedure define the requirements of Medical Device Act reporting. (CI.5f)	
D: Medical Device Act reports, as applicable, are on file in the organization and include validation of submission to the FDA which may include an incident that results in death and when the manufacturer is unknown. (CI.5f)	

CI.5e (cont'd)	The plan addresses: 1) Definition of employees at risk of occupational exposure to TB									
	2) Process for identifying suspected or confirmed cases of TB									
	3) Control of employee exposure when a client is suspected or confirmed as having infectious TB									
	4) Education of all employees to the hazards of exposure to TB at time of hire & annually thereafter									
	5) Pre-employment & subsequent periodic TB screening of employees in accordance with written policy									
	6) Provision of follow up care to employees exposed to TB									
	7) Provision of follow up care to employees who convert to active disease									
	8) Provision of appropriate personal protective equipment when caring for a suspected confirmed TB client									
	9) Provision of work practice oversight to minimize occupational exposure to TB									
	10) Adherence to reporting & record keeping requirements per state/federal law									
CI.5f	Organizational P&P'S address the requirements of the Medical Device Act (MDA) & delineate the mechanisms for reporting incidents which result in serious injury, illness or death									
	1) Reports are filed with the Federal Drug Administration according to regulation									
	2) A designated person is responsible for ensuring compliance with reporting requirements									
	3) Criteria for designation of reportable events are defined									
	4) Written protocols for investigation of events are defined									
	5) Investigative activities are initiated on a timely basis									

EVIDENCE GUIDELINES	CITATION STATEMENTS
D = Documentation S = Survey O = Observation I = Interview D: Medical Device Act reports, as applicable, are on file in the organization and include validation of submission to the FDA which may include an incident that results in death and when the manufacturer is unknown. (CI.5f) D: Written infection control policies and procedures include the elements in CI.5g.	

	6) Accurate documentation of findings include:									
	a) Investigative findings									
	b) Copies of reports sent to manufacturer									
	c) Copies of reports to the FDA									
	7) Retention & retrieval of findings & reports									
	8) In-service education on MDA reporting is provided to staff on an annual basis									
	a) Written curriculum outlines training content									
	b) Records of attendance are maintained									
CI.5g G121	Infection Control P&P's detail systems designed to promote the prevention & control of infections, monitor the occurrence of infections & evaluate the effectiveness of infection control practices									
	1) Current infection control practices & strategies									
	2) Identification & investigation of breaks in technique									
	3) Sources of infection: a) Nosocomial b) Home acquired c) Professional exposure									
	4) Types of infection									
	5) Modes of transmission of infection									
	6) Contributing causes of infection									
	7) Data collection, analysis, tracking & trending of findings									
	8) Reporting requirements per state & federal regulations									
	9) Documented evidence of in-service education for staff includes: a) Dates & times of programs b) Curriculum outline of training content c) Records of staff attendance									
	10) Client/family teaching									
	11) Use of personal protective equipment/supplies									
	12) Accepted hand hygiene techniques									

EVIDENCE GUIDELINES	CITATION STATEMENTS
D = Documentation S = Survey O = Observation I = Interview	
D: Written policy and procedure define the parameters for ensuring the safety, security, and confidentiality of clinical hardcopy, automated, and/or travel records. (Ci.5h).	
D: Written policies and procedures define the parameters that ensure the client's right to access client record information and release client record information. (CI.5h)	
D: Written policy and procedure and local/state/federal regulations dictate the secure retention of all types of clinical records. (CII.5h)	
D: Written policy and procedure details the process for release of information. (CI.5h)	
I: Records administrator or other designated party describes adherence to policy and procedure. (CI.5h)	
I: Staff describe process for accessing policies and procedures. (CI.5i)	
D: Informational materials, written in different languages are available and provided to clients/families as appropriate. (CI.6a)	
I: Administrative/management personnel articulate cultural diversity in the community population and describe the organization's ability to meet special needs. (CI.6a)	
I: Staff members demonstrate awareness and use of available resource materials, and lients/families verbalize knowledge of pertinent resources. (CI.6a)	
I: Clients/families of different cultures acknowledge receipt of language specific materials and care provided by bi-lingual staff, family members and/or the use of interpreters as appropriate and necessary. (CI.6b)	

CI.5h /6	Administrative, financial, client & personnel records are retained & retrievable in accordance with formal record retention policy that is in compliance with organizational policy & local/state/federal law									
	1) Minutes of all official meetings of GB are retained for a minimum of 5 years									
G237	2) Client adult records are retained for a minimum of 5 yrs after the provision of service									
	3) Client records of minors are retained for a minimum of 7 yrs after age of majority is reached									
G112, 240, G241, 310 L183	4) Mechanisms for client access & release of client records are defined									
L178 L179	5) Authorization for client record documentation & entry & signature authorization/ authentication for automated client record system in accordance with individual state law are defined.									
G111,239 L186	6) Process for maintaining safety & security of client records is defined.									
G121	7) Confidential records for employees experiencing an occupational exposure are retained for the duration of employment plus 30 yrs									
G121	8) Annual training records for exposure prone employees are retained for a minimum of 3 yrs									
	9) Client records involved in litigation are retained until after settlement									
CI.5i	Staff members have access to policies & procedures.									
CI.6 G118	Informationals provided to clients/families identifying the availability of organizational & community resources to assist in meeting client needs.									
CI.6a G118	Language specific written materials, as necessary & appropriate, are available for distribution to clients/families									
CI.6b G118	Interpretive services are provided, as indicated & necessary, to ensure accurate communication between client/family/caregiver & other types of health services personnel									

EVIDENCE GUIDELINES	CITATION STATEMENTS
D = Documentation S = Survey O = Observation I = Interview D: Written policy delineates the make up and function of the designated group to review ethical issues. Authority may be self-vested in the governing body, in an independent entity or in an advisory group. (CI.7a,b) I: Administrative/management/staff personnel describe the structure of the ethical group and the process for handling ethical concerns and issues. (CI.7b) D: Meeting minutes document discussions of and actions taken by the group, ass applicable. (CI.7c) I: Administrative/management personnel describe that careful consideration is given to providing a site for relevant research, human subjects involved in any part of research activities provide written informed consent, and that specific parameters for protection of participants and confidentiality of personal information are clearly defined. (CI.8a) D: Policy and procedure establish the parameters for research initiatives as applicable. (CI.8b) D: Current research activities as applicable ensure compliance with CI.8a,b,c,d. I: Administrative/management personnel describe current research initiatives as applicable. (CI.8c) I: Staff describes use of research knowledge which was integrated into practice as applicable. (CI.8e)	

CI.7	**The organization's business, clinical, disease prevention & health promotion activities are conducted according to ethical standards**								
CI.7a	A group of qualified professionals is designated by the GB to review ethical issues as they arise								
CI.7b	Organizational P&P outlines responsibilities of the group & delineates the process for submitting ethical concerns & issues for action								
CI.7c	Meeting minutes clearly document group activities & are referred to the GB for review & final action as indicated & necessary								
CI.8	**The organization considers requests for research in the area of community/public health as appropriate**								
CI.8a	A mechanism is in place for reviewing, processing & approving internal & external research proposals								
CI.8b	Organizational P&P'S define parameters for participation in research activities & investigative studies								
	1) Research protocols, as applicable, for internally & externally sponsored activities are on file								
	2) Potential participants are provided written information regarding the nature, process & benefits of the research outcomes								
	3) Risks associated with the project are clearly delineated								
CI.8c	Organizations participating in research or investigative studies ensure that clients & staff are fully informed								
CI.8d	Formal written consents for participants in research &/or investigative studies are obtained & retained on file in the organization.								
CI.8e	New knowledge from internal or external research is integrated into practice, as applicable.								

EVIDENCE GUIDELINES	CITATION STATEMENTS
D = Documentation S = Survey O = Observation I = Interview D: Current Public Disclosure Policy addresses applicable elements of CII.1a. D: The Client Bill of Rights includes the elements of CII.1b.	

CII.1 .01	The mission drives the activities of the organization & ensures public disclosure, client rights & ethical standards of business & clinical practice									
CII.1a GI17 L106	Public disclosure policy defines availability & accessibility of public information & includes: 1. Ownership information 2. Statement of organization's Mission 3. Licensure & accreditation status as applicable									
CII.1b	A written Client Bill of Rights recognizes, protects & promotes the right of each client to be treated with dignity and respect									
	1) Written P&P'S defines rights & responsibilities of clients									
G102	2) Notice of rights is provided to clients in advance of providing pre-planned care									
G104	3) Client is knowledgeable of right to exercise rights at any time									
G103	4) Organization maintains documentation of compliance of distribution of required information to clients.									
04	5) The client/client's designated representative is authorized to exercise their rights									
G111	6) Confidentiality of client record/data is maintained by the organization									
	7) Access to care/services is based upon non-discrimination									
G106	8) Clients are informed of right to voice complaints/grievances to the organization regarding treatment/ care/service without fear of discrimination or reprisal for doing so									
	9) Organization provides client telephone # of the CHAP hot line, including hours of operation & purpose of the hot line to receive complaints or questions about the organization.									
G109	10) Clients are informed of right to participate in the development of care/ & service plans.									
G113, 114, G115	11) Clients are informed verbally and in writing prior to start of care and as changes occur of billing/ reimbursement methodologies, including fees for services/products provided, direct pay responsibilities, & notification of insurance coverage									

EVIDENCE GUIDELINES	CITATION STATEMENTS
D = Documentation S = Survey O = Observation I = Interview	
I: Clients confirm the timely receipt of the Client Bill of Rights and other admission information. (CII.1c) *Note: Advising clients of their rights is not applicable under conditions of emergency/disaster intervention and mass clinics.*	
D: Documented evidence in the client records confirms receipt of the Client Bill of Rights and other admission information. (CII.1d) *Note: Advising clients of their rights is not applicable under conditions of emergency/ disaster intervention and mass clinics.*	
I: Clients/families articulate understanding of the information provided and describe how they have found the information to be helpful. (CII.1d)	
I: Clients/families describe methods used to contact the organization during regular hours of service, after hours, weekends and holidays. (CII.2a)	
I: Professional, technical, and support staff describe coordination and collaboration between disciplines. (CII.2b)	
I: Professional, technical, and support staff describe coordination and collaboration with sub-contract and/or independent contractor providers of care. (CII.2b)	
I: Clinical supervisors and staff describe the on-call system for services after normal organization hours. (CII.2c)	
O: Testing the after hours on call system validates compliance with organization policy & procedure. (CII.2c)	
D: Written information distributed to clients/families address disasters/emergencies as applicable to the organizations service area. (CII.3a)	
I: Clients/families are aware of their responsibilities in the event of an emergency episode. (CII.3a)	

		NM		Met	Com	NM	RA	Rec	NA	
CII.1c G101, 102	Written admission documents provided to client or the client's representative prior to the start of care or at the time of initiation of care/service ensure organizational compliance with Client Bill of Rights and other regulatory requirements									
CII.1d G101, 102, G103, 104	A reasonable attempt is made & documented to ensure that client & family understand their rights & responsibilities which are reviewed with client prior to start of care or at time of initiation of care and periodically reviewed thereafter									
CII.2	Care, services & products are available to & accessible by the client/client's representative									
CII.2a	Care, services & products are provided within an established time frame, as specified by organizational policy, organizational standards, medical directives or individual physician orders. Consideration is given to the client &/or family in scheduling & providing care									
CII.2b	Collaboration & networking with other providers enhance provision of care & services as applicable									
CII.2c	Supervisory & clinical/service staff demonstrate knowledge of organizational P& P for ensuring delivery of care, services & products to clients									
CII.3 L304	A geographic specific plan defines protocols for prioritizing the delivery of care & services to clients& protects the safety of staff during disasters, emergencies and/or environmentally challenging situations									
CII.3a	Detailed written instructions are given to the client/family to ensure an appropriate & timely response on the part of the client/family in the event of a natural disaster, inclement weather & or other emergent event that might cause an interruption in the provision of services.									

EVIDENCE GUIDELINES	CITATION STATEMENTS
D = Documentation S = Survey O = Observation I = Interview	
D: Staff are oriented to written protocols that ensure the safety and security of personnel. (CII.3b)	
D: Disaster drills are documented as applicable to the organization. (CII.3c)	
I: Administrative/management staff describe roles and responsibilities of personnel during an emergency episode. (CII.3c)	
I: Staff members at all levels demonstrate awareness of responsibilities to ensure the safety of self and others. (CII.3c)	
D: Client records document coordination of care activities, including planning, implementation, monitoring and evaluation of care/service as appropriate. (CII.4)	
I: Clinical/service, financial, and operational staff describes collaboration and support among all disciplines and organizational divisions. (CII.4a)	
O: Organizational planning meetings as available and appropriate. (CII.4a)	
I: Professional, technical, and support staff describe protocols that protect client/family information regarding confidentiality of information, use of travel record and transport and storage of travel record. (CII.5a).	
I: Office staff describe ongoing security of client record information. (CII.5a)	
I: Staff is knowledgeable of the client's right for access to and release of client information. (CII.5a)	
O: Active and inactive client records are maintained in a secure area during working and non-working hours that is inaccessible to unauthorized individuals. (CII.5a)	
S: Random sample of client records reviewed provides evidence of compliance with organizational policy, standards and regulatory requirements. (CII.5c,d)	
O: Automated client record systems include safeguards. (CII.5e)	

CII.3b	Written protocols define management responsibilities in ensuring the safety& security of staff prior to or during an emergent event									
CII.3c L304	Staff are knowledgeable of the practices & procedures relative to emergency preparedness responsibilities & emergent events									
CII.4	**Inter & intra organizational coordination is evident in the planning, implementation, monitoring & evaluation of care & services provided**									
CII.4a G143, 144	Coordination between clinical/service, financial & operational components of the organization is evident									
CII.5 **L176**	**Client records, maintained for each client or client group, are utilized as a tool for coordination of services, as a legal document that is descriptive of care & services provided & as a resource document for billing & reimbursement**									
CII.5a 11,239, G310 L186	All protected health information or client records, hardcopy or automated, are kept confidential and safeguarded against loss or unauthorized use in accordance with organizational policy & local/state/federal regulations									
CII.5b G112, 240	Clients have access to their records & are informed of the process									
CII.5c G235, 236 L176, 177 L182, 184 L185	The client record documentation provides client information specific to care & services/products provided, current client status & progress toward goals & outcomes of care									
CII.5d G166, 239 L178, 179	Entries to client record documentation is made only by authorized staff & in accordance with organizational P&P									
CII.5e G239 L186	Automated client record systems ensure consistent & ongoing security & protection of data									
CII.5f L176	The format for maintenance of client records is reviewed & updated as necessary									
CII.5g G125, 126	Organizations with alternate sites ensure consistent documentation, communication, coordination & retrieval of significant administrative & client/family information									

EVIDENCE GUIDELINES	CITATION STATEMENTS
D = Documentation S = Survey O = Observation I = Interview	
SI: Client records administrator describes process for ensuring consistent, ongoing validation and protection of automated records data including prevention of lost data due to equipment failure and storage of backed-up files. (CII.5e)	
I: Evidence is provided validating periodic review and updating of the record format used. (CII.5f)	
I&O: Managers/staff describe and demonstrate compliance with policy and procedure governing the coordination, transport, and security of information shared with and between alternate sites. Staff describe the type of information that is maintained and the procedures for coordination, communication, exchange, and retrieval of required information with the parent organization. (CII.5g)	
D: Data reflect measurement of quality of services outcomes. (CII.6a)	
I: Performance improvement manager describes rationale for the performance improvement process and the definition of specific client/service outcomes. (CII.6b,d,e)	
D: A structured framework exists. (CII.6c)	
D: A client satisfaction survey for the current year is available for review and includes at a minimum client satisfaction with care and services provided and satisfaction with providers of care. (CII.6f)	
I: The organization describes the mechanism for monitoring client satisfaction. (CII.6f)	
D: Evidence exists of utilization of performance improvement findings to resolve problems and improve quality of service/products. (CII.6g)	
D: Organizational committees and governing body minutes document reporting of trends of performance improvement findings. (CII.6h)	

CII.6	**A comprehensive Performance Improvement process integrates the organization's Mission & promotes an organizational wide approach that selects, reviews & analyzes outcomes specific to organizational needs & scope of services/products**								
CII.6a	Quality is defined and measured in terms of client/service outcomes								
CII.6b	Specific outcomes are targeted for improvement or replication								
CII.6c L141, 142	The organization develops a structured framework for the investigation of target outcomes								
CII.6d	The organization identifies outcomes to benchmark by utilizing internal standards/ processes/ protocols, practice/ service guidelines, industry research &/or best practices								
CII.6e G249 L145	The organization continually evaluates progress toward outcomes & identifies new areas to improve or replicate as indicated by results of data analysis								
CII.6f	A process for monitoring & measuring the satisfaction levels of clients is conducted at least annually								
CII.6g G245 L142 L143 L144 L145	Performance Improvement findings are: 1) Used to resolve identified problems 2) Used to improve quality of services/products 3) Incorporated into program planning/modification/ enhancement								
CII.6h G245, 246 L142 L143 L145	Trends of Performance Improvement findings are reported to appropriate organizational committees & the GB								
CII.7	**The health & safety of employees & clients is promoted & enhanced through education, current application of infection control practices & implementation of appropriate safety measures**								

EVIDENCE GUIDELINES	CITATION STATEMENTS
D = Documentation S = Survey O = Observation I = Interview **D:** Personnel records include evidence of adherence to regulatory requirements of Federal OSHA and CDC. (CII.7a) **D:** Written plans define parameters for exposure control, adherence to universal precautions, adherence to work practice controls, HBV prophylaxis and TB exposure control. (CII.7b) **D:** Potential for employee exposure is determined by job classification, which defines the potential for risk and includes: a) Definition of types of tasks and/or procedures that place an employee at risk for exposure. b) Description of job classifications in which all employees have the potential for occupational exposure. c) Description of job classifications in which employees have the potential for occasional exposure. d) Description of job classifications in which employees have no risk for occupationally related exposure. (CII.7c) **O:** Staff demonstrate adherence to standard precautions as determined by organizational policy: a) Use of gloves b) Use of and accessibility to masks and protective eyewear c) Use of protective gowns and aprons d) Hand hygiene/hand washing techniques including the use of chemical substances e) Techniques for minimizing needle sticks f) Use of puncture resistant sharps containers g) Proper transportation and storage of sharps h) Disposal of contaminated supplies and equipment on site (CII.7d)	

CII.7a G121 L105	Adherence to regulatory requirements that address the health & safety of employees & clients & their protection from blood borne pathogens is validated 1) State &/or Federal OSHA mandates as applicable 2) CDC recommendations & guidelines									
CII.7b L305, 308	The organization implements its written Exposure Control Plan									
CII.7c	The potential for occupational exposure is determined for all job classifications in accordance with state/federal & Occupational Health & Safety Administration (OSHA) mandate									
CII.7d	Adherence to the use of Standard Precautions by job classification is documented									
CII.7e	Adherence to work practice & engineering controls is evident in practice									
	1) Physical work sites are maintained in clean & sanitary condition									
	2) Use of disinfectant solutions									
L307	3) Handling, transporting, storage & processing of soiled/contaminated materials, supplies & equipment									
	4) Use of non-leak infectious waste containers as applicable									
L307	5) Identification & labeling of infectious waste as applicable									
CII.7f	Employer & employee responsibilities relating to Hepatitis B prophylaxis (HBV) are defined in writing & include:									
	1) HBV vaccination & exposure follow-up program									
	2) Employer/employee responsibilities									
	3) Declination of HBV statement is signed by employees as applicable & filed in personnel health records									
	4) Complete & detailed documentation of all exposure events									
	5) Confidential records are maintained on HBV vaccination & post exposure follow up									

EVIDENCE GUIDELINES	CITATION STATEMENTS
D = Documentation S = Survey O = Observation I = Interview	
S: Random sample of employee records provides evidence of compliance with Hepatitis B (HBV) prophylaxis program. (CII.7f)	
I: Designated person describes procedure followed to ensure compliance with investigative requirements and protection of the rights of the employee who has experienced an occupational exposure. (CII.7f)	
D: Education and training records document compliance with training requirements. (CII.7g)	
D: Occupational exposure information is maintained in confidential records that are retained for the duration of employment plus thirty (30) years. (CII.7h)	
I&O: Clinical, technical and support staff describe potential hazards in the home setting identified during the assessment of the client's living environment. (CII.7k)	
D&I: Evidence exists that the organization monitors and reports information related to adverse events. (CII.7l) Adverse events include but are not limited to: • Provision of care errors • Unusual occurrences • Vehicular crashes • Other types of accidents or injury • Safety hazards Serious Adverse Events include but are not limited to: • Unexpected death not resulting from the clients medical condition • Loss of body part • Permanent or partial loss of body function • Blindness (CII.7l – Cont'd next page)	

CII.7g	Education & training programs ensure that: 1) New employee orientation addresses all aspects of the Exposure Control Plan 2) Annual training is mandated for all exposure prone employees based on applicable job classification									
CII.7h	The organization demonstrates compliance its Occupational Exposure Control policies, plan, & procedures									
	1) HBV is provided at no cost to all employees, potentially subject to occupational exposure, within 10 working days of assignment									
	2) Provision of personal protective equipment to employees with potential for an occupational exposure as as determined by job classification									
	3) A confidential medical evaluation & follow-up care is offered to employees who experience an occupational exposure:									
	a) Counseling									
	b) Testing of source individual if allowable under state &/or local law									
	c) Blood testing of exposed employee with written consent if medically indicated									
	4) Accurate, confidential & timely documentation of:									
	a) Circumstances leading to exposure									
	b) Routes of exposure									
	c) Medical follow up									
	d) Opportunity for counseling									
	e) Other related interventions as indicated & necessary									
CII.7i	The organization demonstrates compliance with its TB Exposure Control Plan									
CII.7j	The organization demonstrates compliance with its safety program to monitor environmental conditions for identifying potential hazards/risks									
CII.7k	A routine assessment is made of the client's living environment to identify & evaluate potential safety hazards related to the physical space, as applicable									

EVIDENCE GUIDELINES	CITATION STATEMENTS
D = Documentation S = Survey O = Observation I = Interview	
D&I: Evidence exists that the organization monitors and reports information related to adverse events. (CII.7l)	
Reports document data on adverse events that predispose the organization to real or potential liability. • Data are collected within 30 days of an event • Data are analyzed within 60 days of the event to determine underlying factors leading to the adverse event • Performance Improvement processes, as applicable, include evidence of organizational changes subsequent to an adverse event (CII.7l)	
D: Medical Device Act reports, as applicable, are on file in the Organization and include validation of submission to the FDA. (CII.7m)	
I&O: Staff demonstrate knowledge of and compliance with the organizational infection control practices and procedures. (CII.7n)	
D: Examples of complaint documentation logs. (CII.8a)	
D: Formal documentation of investigative findings and reports as applicable. (CII.8a)	
D: Resolution information is documented as communicated to the complainant. The communication to complainant may be in writing or by telephone. (CII.8b)	
I: Staff describes an understanding of the complaint process. (CII.8c)	

CII.7l	A system is in place for monitoring & reporting information related to adverse events that endanger the health & safety of clients &/or employees & predispose the organization to real or potential liability									
	1) Adverse Events & Serious Adverse Events are defined in organizational policy									
	2) Data for all events is collected/ analyzed/tracked/ trended as a part of risk management									
	3) Corrective actions are implemented & evaluated as indicated & necessary									
	4) Adverse event reports detail each episode & are distributed to advisory boards & accrediting bodies as applicable									
CII.7m	The organization demonstrates compliance with its P & P's for the Medical Device Act (MDA)									
CII.7n G121 L105, 305 L327	The organization demonstrates compliance with its infection control P & P's:									
CII.8	**Client/family complaints/ concerns are responded to & resolved in a timely manner**									
CII.8a G107	The complaint process includes intake, investigation, corrective action as applicable, complaint resolution, written reports, organizational trending & follow-up									
CII.8b	Resolution/outcome information is communicated to the complainant									
CII.8c	Staff are aware of organizational mechanisms for receiving & resolving complaints									

EVIDENCE GUIDELINES	CITATION STATEMENTS
D = Documentation S = Survey O = Observation I = Interview D: Policy, procedure and recruitment documents support a non-discriminatory approach to hiring. (CIII.1a) I&O: Interviews with staff and observation of client practice/service validate adherence to discipline specific practice standards and to regulatory guidelines and requirements specific to respective areas of responsibility. (CIII.1b) I: Staff confirm clear understanding of responsibilities and lines of authority. (CIII.1c) I: Management explains turnover rate variances as applicable, and describes impact on recruitment and retention activities. (CIII.1d) D: Employee records validate the opportunity for a formal exit interview for terminating employees in accordance with organizational policy and procedure. (CIII.1e) I: Employees validate receipt of conditions of employment and describe the process for obtaining personnel related information. (CIII.1f) D: Employee files are complete and current and include documents specific to CIII.1g. Evidence of verification of education/training may include copies of diplomas, transcripts or telephone validation. (CIII.1g)	

UP III	ADEQUATE RESOURCES: HUMAN, FINANCIAL & PHYSICAL								
F1	The organization has adequate & appropriate human resources to meet caseload & workload demands								
CIII.1a	A non-discriminatory recruitment & selection process, as defined in P&P'S, is adhered to								
CIII.1b G121	Personnel are employed & assigned responsibilities commensurate with their education & experience								
CIII.1c	Job descriptions for each employee category delineate lines of authority & reporting responsibilities, duties to be performed & educational & experiential qualifications specific to the position								
CIII.1d	Employee turnover rates are monitored, tracked & trended as applicable								
CIII.1e	The opportunity for exit conferences are: 1) Offered to terminating employees as applicable 2) Documented & trended as applicable								
CIII 1f.	Personnel policies/conditions of employment are provided to employees:: 1) At time of hire and 2) Thereafter, as updates/revisions are needed								
CIII.1g	Evidence of the following employee information is maintained in accordance with organizational policy & regulatory guidelines:								
G141	1) Individual job qualifications								
	2) Verification of education/training								
	3) Certification for specialty areas of practice as applicable								
	4) Statement of formal training for non-professionals								
	5) Two (2) reference checks								
	6) Pre-employment interview(s)								
G141 L174	7) Current license/certification as applicable								
	8) Validation of competency skills testing as applicable								
G211, 212	a) Time of hire								
	b) Annual								

EVIDENCE GUIDELINES	CITATION STATEMENTS
D = Documentation S = Survey O = Observation I = Interview	
O: Specified personnel documents are secured in accordance with organizational policy. (CIII.1h)	
D: Annual evaluation form addresses elements of CIII.1i as applicable for the job category.	
I: Sample of employees and supervisory staff personnel records confirm adherence to the annual evaluation process. (CIII.1i, 1j)	
D: A written plan details the orientation of new personnel and for personnel assigned to a new job classification. Components of the orientation plan may include mission and purpose of the organization, table of organization, lines of authority and responsibility, hours of work, job-related responsibilities, and personnel policies. (CIII.1k)	
I: Recent hires describe their orientation as comprehensive and pertinent to meeting job responsibilities. (CIII.1k)	
I: Staff assigned to a new job classification describe their orientation to the new responsibilities. (CIII.1k)	

G214	9) Validation of performance evaluation at end of probation & annually									
	10) Validation of malpractice coverage for independent contractors									
	11) Validation of completion of orientation (new & reassigned personnel)									
	12) Validation of signed & dated confidentiality statements									
	13) Validation of in-service/ continuing education participation as applicable									
	14) Validation of exit interview as applicable									
	15) Miscellaneous items per state, federal or organizational requirements									
	16) Criminal background checks in accordance with organization P & P and local and/or state law									
	17) Immigration & naturalization statement (I-9)									
CIII.1h	Specified personnel documents and employee health reports may be retained in separate files per organizational policy									
CIII.1i '214	An annual written performance evaluation process is completed on all employees by their respective supervisor & includes:									
	1) Supervisor assessment of employee performance in accordance with established criteria (Job Description)									
	2) Achievement of previously established goals									
	3) On-site evaluation reports/competency testing for clinical/field/service staff									
	4) A signed, dated validation of the evaluation process by the employee & employer representative									
CIII.1j	An annual performance evaluation process provides an opportunity for active participation by employees through:									
	1) Employee development planning/new goal setting									
	2) Employee response to evaluation									
CIII.1k 140 161	A written plan details the orientation process for all new & reassigned employees which addresses applicable elements pertinent to each job classification									

EVIDENCE GUIDELINES	CITATION STATEMENTS
D = Documentation S = Survey O = Observation I = Interview I: Staff validate receiving applicable hours of in-service programming and describe the types of experiences available to them. (CIII.1l) O: Federally required in-services include OSHA mandated. Staff Development opportunities may include: independent study, satellite learning, specialized conferences, formal courses of study and mentoring. (CIII.1l) D&I: Policy and managers describe the process for assuring that personnel are identified. Service contracts with organizations detail the process that sub-contract organization will assure sub-contract organization identification of staff. (CIII.1m) D: A review of randomized sample of written contracts for the provision of care, services and/or products validates adherence to CIII.2,a,b I: Contract manager or other designated party describes the ongoing management and control of contractual agreements. (CIII.2a)	

CIII.1l G134, 178, G189, 192, 100, 215 140, 161	The organization shall provide in-service and staff development as needed and as required by local/state/federal regulations & national and/or professional standards as applicable									
CIII.1m	Personnel are provided with identification badges or are identified as working for the organization									
CIII.2	**Formal written contracts, executed by the primary organization with other professionals & /or other entities for the provision of care services & products to clients of the primary organization, detail specific responsibilities of the parties involved**									
CIII.2a G146 L115, 117 L126, 189	Written service contracts with individuals &/or other entities are signed & dated by authorized principals of each party & are reviewed annually									
CIII.2b	The executed document stipulates the terms of the contract which includes:									
G123, 142 L118	1) Specific services/products to be provided									
G142 L124	2) Contractor is required to adhere to applicable primary organization's P&P's									
G142 G 231 L123 L189	3) Assurance by the contractor of the education, training, qualifications, & identification of personnel designated to provide care, services & products									
G142 L120	4) Mechanisms for the contractor parties to participate in Performance Improvement activities as applicable									
G142 L122	5) Procedures for the documentation & submission of documented notes that verify the provision of services/products in accordance with the written service contract									
L124 L125	6) Procedures for the submission of bills & related information & reimbursement for care, services & products provided									
	7) Effective dates of the contract, including terms of renewal &/or termination									

EVIDENCE GUIDELINES	CITATION STATEMENTS
D = Documentation S = Survey O = Observation I = Interview	
D: Organizational policy and procedure detail the fiscal activities and responsibilities of the organization. (CIII.3a)	
I: The chief financial manager confirms credentials and experience background for the responsibilities assigned and describes the budget planning process. (CIII.3b)	
D: Governing Body minutes confirm approval of budgets and other financial agenda items referred to the Governing Body. (CIII.3c)	
D: The organization has current operating budget and capital expenditure plan. (CIII.3d)	
D: Financial, statistical and productivity reports are used to facilitate oversight of the organization's operations. (CIII.3e)	
I: The chief financial manager describes the use of financial, statistical or productivity reports. (CIII.3e)	
I: The chief financial manager validates the adequacy of insurance coverage. (CIII.3f)	
D: Review of annual financial review validates that the review was conducted by an organization external to the organization within the most recent twelve month period. (CIII.3g)	
D: Financial reports detail the information used to measure operational performance. (CIII.4a,b)	
I: The chief financial manager or other designated party describes the effectiveness of the financial management information systems, the types of reports generated and their use, and internal financial controls. (CIII.4a,b,c)	

CIII.3	**The organization's sources of financial support are managed & monitored on an ongoing basis to ensure the availability of adequate funding**								
CIII.3a L108, 125	Financial P&P's govern fiscal activities of the organization								
CIII.3b	The chief financial manager has the appropriate qualifications, credentials & expertise to oversee, manage & direct the fiscal operations of the organization								
CIII.3c G147, 148	Major participants in developing & monitoring the budgetary process include the GB, the chief executive, the chief financial manager, program directors & other designated staff as appropriate								
CIII.3d G147, 148	The operating budget & operating capital expenditure plan is developed using methodologies commensurate with the scope & complexity of the organization's services, programs, & products & is used to forecast financial & operating successes & challenges								
CIII.3e	Financial management tools are used to provide operational feedback to administrative & management personnel, financial committees & the GB								
CIII.3f	Adequate insurance coverage is maintained								
CIII.3g	An annual external review is required & conducted								
CIII.4	**A financial management information system is used to document and monitor all financial components and provide appropriate and timely reports to all levels within the organization.**								
CIII.4a	The financial reporting system produces detailed data regarding actual transactions specific to care, services & products provided by each program including site/location activity								
CIII.4b	Periodic financial statements contain key financial indicators & show a reasonable match between revenue & expense line items								

EVIDENCE GUIDELINES	CITATION STATEMENTS
D = Documentation S = Survey O = Observation I = Interview D: Organizational financial procedures used for internal control may include segregation of duties, reconciliation of control accounts, approval levels for disbursements and adjustments, collection of accounts receivable, budgeting, receipt of funds, disbursement of funds, cash and asset account reconciliation and cash management. (CIII.4c) I: Financial/billing staff confirms timely billing procedures ongoing monitoring of accounts receivable, implementation of collection efforts as appropriate, and adherence to accounts receivable guidelines. (CIII.4d) D: Financial reports include payroll and vendor disbursements in accordance with CIII.4e.	

CIII.4c	Internal financial controls are in effect									
149	1) Internal audit procedures & annual review of budget are conducted 2) Adherence to organizational financial P&P's is monitored									
CIII.4d	Reimbursable services are billed on a timely basis in accordance with designated fee structures & are monitored, tracked & aged									
CIII.4e	Payroll & vendor disbursements are recorded & processed in a structured & timely manner									

EVIDENCE GUIDELINES	CITATION STATEMENTS
D = Documentation S = Survey O = Observation I = Interview D: Applicable statements indicating compliance with OSHA, CDC, ADA, are available and may include: 1) Fire drill and health inspection reports indicate compliance. 2) Certificates of occupancy are posted in accordance with local requirements. 3) Fire and emergency exits are clearly detail areas of entrance and egress. 4) Hazardous area access is controlled. 5) Hazardous chemicals and solutions are properly labeled and kept in locked storage. 6) Adequate space and privacy is provided to employees and clients receiving services. 7) Facilities are barrier free and/or special arrangements are made to provide access as indicated and necessary. 8) Safety and security procedures for employees are implemented as necessary. (CIII.5a) O: Tour of facility validates compliance with OSHA, CDC, and ADA guidelines and applicable local requirements. (CIII.5a) D&I: MIS manager or other designated party explains and demonstrates how data are collected, processed and secured on the off site. (CIII.6a) I: Management describe how information system is used to ensure organizational accountability. (CIII.6)	

CIII.5	**Physical facilities are adequate to support the operations**									
CIII.5a G118 L124 L305	Physical facilities meet the OSHA (Federal/State), CDC, ADA &/or state or local regulations for environmental protection & safety of employees & recipients of service									
CIII.6	**A management information system is utilized to ensure accountability at all levels of the organization**									
CIII.6a	A manual or automated system utilizes established standards & defined data elements for the collection & processing of information									

EVIDENCE GUIDELINES	CITATION STATEMENTS
D = Documentation S = Survey O = Observation I = Interview	
I: Management and staff describe the planning process. (CIV.1a)	
I&O&D: The assessment of the strengths, weaknesses, opportunities and threats may include the following components: 1) Asses and analyze service area demographics. 2) Maintain current knowledge of organization's market penetration. 3) Identify new and/or changing consumer and community needs. 4) Collect data and information for analysis. 5) Garner input from all levels of staff. 6) Determine organizational priorities. (CIV.1b)	
I: The CEO and/or governing body representative describes the long term vision and goals for the organization. (CIV.1b)	
D: The organization provides evidence that a current annual evaluation was conducted timely and in accordance with its organizational policies and process. (CIV.2a)	
D: The annual evaluation report validates the inclusion of service/product, risk management, human resources and financial and operational components in the evaluation process. (CIV.2b)	
I: Administrative/management personnel describe how the complexity of the organization relates to data collection and utilization. (CIV.2b)	
D&I: Minutes and interview confirm that the annual evaluation report was presented to the appropriate advisory and governing bodies. (CIV.2d)	

CIV	*LONG TERM VIABILITY*									
CIV.1	**Strategic planning reflects the organizational mission & includes a comprehensive evaluation of both internal & external environments**									
CIV.1a	Current budgetary, business & marketing activities are integrated into the process									
CIV.1b	An assessment of the organization's strengths, weaknesses, opportunities & threats is conducted on a periodic basis									
CIV.2	**An annual evaluation of the organization provides the basis for future planning**									
CIV.2a G242, 243 G249	Organizational policies drive the process for the annual program evaluation by an authorized group & identify the components to be evaluated									
CIV.2b G245 G 249 L142	The complexity of the organization & the scope of care, services & products provided define the parameters for data collection & utilization and includes: 1) Service/product data 2) Risk management data 3) Human resources data 4) Financial data									
CIV.2c	Variances from usual & expected patterns of performance are analyzed & explained									
CIV.2d G153, 154, G246 L143	The Annual Evaluation Report is presented to advisory & governing bodies as appropriate									
CIV.2e G247	The Annual Evaluation Report is retained as an administrative record									

PHARMACY STANDARDS OF EXCELLENCE
2004-2005 EDITION

SITE VISIT WORKBOOK

Site Visit Dates:_____ **to**_____

Name of Organization:_____

Address: _____ Telephone:_____

_____ Fax:_____

_____ E-mail:_____

Contact Person: _____

Title: _____

Medicare # _____ Medicaid #_____

Other # _____

Visit Type _____

SITE VISITOR CITATIONS:

Commendations	_____	New Required Actions	_____
Former Required Actions	_____	New Recommendations	_____
Met	_____	Medicare Tags	_____
Continued as RA	_____	Deemed Visit (√)	_____
Continued as Rec	_____	Modified CORE (√)	_____

Site Visitor Name	Signature	Initials
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____

EVIDENCE GUIDELINES	CITATION STATEMENTS
D = Documentation S = Survey O = Observation I = Interview	
D: A printed definition of the organization's scope of products and services is available. (DI.1)	
D: Governing body minutes document actions taken on the scope of products and services statement: (a) Review and approval within the past twelve months. (b) Revisions and updates as applicable. (DI.1a)	
I: Management and staff describe the process for making the scope of products and services statement available upon request. (DI.1b)	
D: Required County/State/Federal licenses, authority documents, and Medicare/ Medicaid reimbursement certification (if applicable) are current as required. (DI.2a) *Note: County/State specific licenses may include Sellers Permit, Occupational License, etc. (DII.2a7)*	
D: Review of recent findings of other reviewing bodies confirm compliance. (DI.2a)	
D: The disclosure statement is current, signed and dated by the chief executive and is on file. (DI.2b)	

	PHARMACY STANDARDS	Visit NM	SS	Current Visit						COMMENTS
				NA	Met	Com	NM	RA	Rec	
DI.1	STRUCTURE & FUNCTION									
DI.1	A written statement by the Pharmacy Organization identifies the scope of products and services provided to clients.									
DI.1a	The scope of services statement is periodically reviewed, revised and approved by the governing body but no less than every twelve (12) months.									
DI.1b	The pharmacy's scope of services statement is made available upon request to clients, referral sources and other interested parties.									
DI.2	The Pharmacy Organization has the structure and functional mechanisms necessary to accomplish its stated scope of services.									
DI.2a	The Pharmacy Organization has the legal authority to operate and is in compliance with local, state and federal regulations.									
	1) State Board of Pharmacy License									
	2) Business License									
	3) DEA Narcotic License									
	4) d/b/a, Trade Name registration, if applicable									
	5) Tax ID number									
	6) Medicare & Medicaid provider numbers, where applicable									
	7) Specific county and state required authority									
DI.2b	The Pharmacy Organization is required to prepare and maintain a current written disclosure statement signed by the chief executive, addressing applicable elements as frequently as required by state regulations but no less frequently than every three years.									
	1) Names and addresses of individuals or corporations having a combined direct or indirect ownership or controlling interest of 5% or more in the organization									
	2) Names and address of subcontractors in which the organization has a direct or indirect ownership of 5% or more									
	3) Names and addresses of individuals, who are related as spouse, parent, child or sibling to individuals described in (1) and (2) above									
	4) Names and addresses of individuals in (1), (2), and (3) above with an ownership or controlling interest in a Medicare or Medicaid facility									

EVIDENCE GUIDELINES	CITATION STATEMENTS
D = Documentation S = Survey O = Observation I = Interview	
D: Minutes or other formal governing body documents reflect that the governing body authorized an advisory committee. (DI.2c) *Note: Advisory Committee may be the governing body as a whole, a subcommittee of the governing body or a separate committee.*	
D: Membership in the advisory committee includes a physician, a pharmacist, a registered nurse and at least one community representative. (DI.2c)	
D: Official documentation or minutes reflect annual review of policies and evaluation of the Pharmacy program. (DI.2c)	
I: Management and staff describe and cite examples of how current clinical and organizational data are assessed and used in revision of policies and practices. (DI.2d)	
D: A current organizational chart is available and clearly delineates the lines of authority and accountability for all organizational positions. (DI.3a)	
I: Staff members are familiar with the organizational chart and state their individual lines of authority and accountability. (DI.3a,3b)	

	PHARMACY STANDARDS	Visit NM	SS	Current Visit						COMMENTS
				NA	Met	Com	NM	RA	Rec	
	5) Names and addresses of officers, directors or partners									
	6) The circumstances of any criminal offense conviction involving Medicare/Medicaid programs on in (1), (2) or (3) above and/or, on the part of any managing employee of the organization									
	7) The dates of any changes in ownership or control during the previous twelve (12) months									
	8) The dates of anticipated changes of ownership or control in the next twelve (12) months									
DI.2c	An Advisory Committee of professionals is authorized by the governing body to advise the organization on policies and to evaluate the Pharmacy Program.									
	1) Responsibilities of the committee include establishment and annual review of pharmacy policies and participation in the annual evaluation of the Pharmacy program.									
	2) Membership of the committee includes a physician, a pharmacist, a registered nurse and at least one community representative who is not an employee									
	3) Committee meeting minutes reflect the committee's fulfillment of its responsibilities									
	4) The Advisory Committee meets at least once annually.									
DI.2d	Systems exist for obtaining and integrating the most current information into the professional practice to be used in planning, evaluation and decision making in all aspects of the program									
DI.3	Intra-organizational relationships of the Pharmacy Organization are clearly defined in writing.									
DI.3a	A current organizational chart illustrates the lines of authority and accountability for all administrative, professional, technical, clinical and clerical personnel.									
DI.3b	The complexity of the Pharmacy organization's administrative structure is appropriate for efficient delivery of product and service.									

EVIDENCE GUIDELINES	CITATION STATEMENTS
D = Documentation S = Survey O = Observation I = Interview **D: Pharmacy Program Director's resume, diploma, reference checks and current professional license verify compliance with requirements for the position. (DI.4a, DI.4b)** *Note: The Pharmacy Program Director may be a regional position in multi-state organizations. In that instance, the Program Director would have a current active Pharmacist license in a state. The Pharmacist in Charge at the specific site will have an active Pharmacist license in that state. The Pharmacy Program Director and the Pharmacist in Charge may be the same or separate position in the organization..* **I: Pharmacy Program Director demonstrates knowledge of local, state and federal pharmacy regulations. (DI.4b)** **D: The Pharmacy Program Director's job description and/or policies include responsibilities as specified in elements 1-11, or the responsibilities are clearly delegated in writing to other specific positions. (DI.4c)** **I & O: The Pharmacy Program Director demonstrates understanding of his/her role. (DI.4c)**	

	PHARMACY STANDARDS	Visit NM	SS	Current Visit						COMMENTS
				NA	Met	Com	NM	RA	Rec	
DI.4	Authority and responsibility for the overall executive management of the Pharmacy Organization is vested in qualified individuals.									
DI.4a	The Pharmacy Program Director is a graduate of a pharmacy program accredited by the American Council of Pharmaceutical Education or has passed a Foreign Pharmacy Graduate Equivalency Examination given by the National Association of Boards of Pharmacy, is currently licensed as a Pharmacist in the state.									
DI.4b	A qualified pharmacist with appropriate knowledge, expertise and experience is responsible for the management, direction, coordination and general supervision of all professional services.									
DI.4c	The Pharmacy Program Director is responsible for the following areas either directly or by clear delegation:									
	1) Organizing and directing the Pharmacy program's operations to assure the availability of services and products provided									
	2) Assuring adequate inventory of pharmaceuticals and supplies necessary to compound and dispense prescriptions appropriately, including periodic inspection for outdated products.									
	3) Assuring all equipment utilized in the delivery of the organization's products and services is properly maintained									
	4) Assuring pharmacy services are provided in compliance with applicable laws, regulations, accreditation standards and ethical standards of practice									
	5) Assuring adequate and appropriate staffing, including recruitment, orientation, in-service education and completion of annual performance appraisal									
	6) Coordinating with other program areas and managers as appropriate, consistent with organizational structure									
	7) Assuring the implementation of a pharmacy performance improvement program including evaluation of the home pharmacy program services									

EVIDENCE GUIDELINES = Documentation S = Survey = Observation I = Interview	CITATION STATEMENTS
Written policy and procedure defines assignment of administrative responsibilities in the absence of the Pharmacy Program Director. (DI.4d)	
Designated alternate to the Director understands his/her role and describes experiences specific to the alternate roles. (DI.4d) *DI.4 may appear to be a duplication of CI.4; however, CI.4 pertains to the CEO of an organization, and DI.4 pertains to the Pharmacy Program Director, which may be the same or separate position in the organization.*	
Policies reflect the current practice, professional standards of service, and scope of service. (DI.5a)	
Pharmacy administrative policies and procedures at a minimum address items 1-4. (DI.5b)	
Pharmacy operational policies and procedures at a minimum address items 1– 25. (DI.5c)	
Policy is available and includes temperature, light and security. (DI.5c.1)	
Policy is available when the pharmacy has a contractual relationship with a nursing agency. (DI.5c.8)	

	PHARMACY STANDARDS	Prior Visit NM	SS	Current Visit						COMMENTS
				NA	Met	Com	NM	RA	Rec	
	8) Assuring Drug Control system consistent with policies and regulatory requirements									
	9) Assuring Drug Dispensing system consistent with policies and regulatory requirements									
	10) Assuring appropriate pharmacy supervision at all times									
	11) Assuring safe and appropriate service policies are developed and implemented									
DI.4d	A qualified individual is designated in writing to act in the absence of the Pharmacy Director.									
DI.5	Pharmacy policies and procedures reflect an emphasis on quality and ethical practice, relate directly to the scope of the Pharmacy program, and ensure client rights, and ethical standards of business and clinical practice.									
DI.5a	Organizational literature, policies and procedures accurately reflect the current practice, current professional standards of service and scope of the Pharmacy program.									
DI.5b	Pharmacy Program administrative policies and procedures include:									
	1) Regulatory Compliance									
	2) Capital Short-fall Contingency Plan									
	3) Pharmacy Reference Materials									
	4) Annual Evaluation									
DI.5c	Pharmacy Program operational policies and procedures covering the scope of services provided are developed and include at a minimum:									
	1) Storage of final pharmaceutical products									
	2) First dose new drug administration									
	3) Handling investigational drugs									
	4) Client/caregiver instruction									
	5) Timely assessment of client eligibility and provision of service									
	6) Notification of referral source if client does not meet admission criteria									
	7) Delivery of services/products, as applicable									
	8) Contents, dispensing and maintenance of infusion emergency kits									
	9) Acquisition, storage, disposition & dispensing of controlled substances									
	10) Selection, maintenance, use & control of infusion control devices for drug administration, as applicable									
	11) Client identification confirmation									

EVIDENCE GUIDELINES	CITATION STATEMENTS
D = Documentation S = Survey O = Observation I = Interview	
D: Pharmacy operational policies and procedures at a minimum address items 1– 25. (DI.5c)	
D: Pharmacy clinical policies and procedures at a minimum address items 1 –6. (DI.5d)	
D: Pharmacy quality improvement policies and procedures at a minimum address items 1-4. (DI.5e)	
D: Written policy is available for first dose drug. (DI.5f)	

	PHARMACY STANDARDS	Prior Visit NM	SS	Current Visit						COMMENTS
				NA	Met	Com	NM	RA	Rec	
	12) Availability of latex-free supplies									
	13) Prescription labeling									
	14) Materials/Inventory Management									
	15) Equipment cleaning, testing and tracking									
	16) After Hours Coverage									
	17) Dispensing Records									
	18) Sterile Admixture Procedures for monitoring for medication errors, surface testing, environmental air sampling and product sterility									
	19) Preparation of injectables from sterile solutions									
	20) Preparation of injectables from non-sterile powders									
	21) Preparation of respiratory drugs from non-sterile powders									
	22) Clinical competency testing									
	23) Competency testing of sterile product preparation									
	24) Medication Error									
	25) Recall									
DI.5d	Clinical policies and procedures consistent with professional standards of practice are developed and include at a minimum the following:									
	1) Client Assessment									
	2) Medication Assessment									
	3) Drug Profile Review									
	4) Care Planning, as appropriate									
	5) Development of a comprehensive care plan									
	6) Clinical monitoring									
DI.5e	Quality Improvement policies and procedures consistent with professional practice and regulatory mandates are developed and include at a minimum:									
	1) Performance Improvement Plan									
	2) Structure and routine maintenance of compounding areas									
	3) Maintenance of Laminar Flow Hood									
	4) Infection control, safety for preparation, dispensing, disposal of pharmaceuticals									
DI.5f	Policies identify when a physician or other qualified professional is required to be present for the administration of the first dose of a new drug to detect, monitor and respond to adverse drug reactions.									

EVIDENCE GUIDELINES	CITATION STATEMENTS
D = Documentation S = Survey O = Observation I = Interview	
D: Meeting minutes document discussions of and actions taken by the group, as applicable. (DI.6a)	
I &O: Staff demonstrates knowledge of and compliance with reimbursement and regulatory guidelines. (DI.6b)	
I: Pharmacy Director/pharmacists describe the process for assuring that clients are fully informed and provide written consent prior to participating in research or investigational studies. (DI.7a)	
D: Written contract or agreements pertaining to Pharmacy educational experiences for non-employees (i.e., students) exist as applicable. (DI.7b)	
D & I: Documents and interviews validate that current research initiatives exist as applicable. (DI.7c)	
D & I: Pharmacy employees publish research findings as applicable. (DI.7d)	

	PHARMACY STANDARDS	Prior Visit NM	SS	Current Visit						COMMENTS
				NA	Met	Com	NM	RA	Rec	
DI.6	The Pharmacy Organization's business and clinical activities are conducted according to ethical standards.									
DI.6a	A designated and qualified group of professionals/individuals address ethical issues relating to the business and clinical practices of the Pharmacy Organization. The issues include but are not limited to:									
	1) Care delivery issues									
	2) Product and service related issues									
	3) Billing and collecting issues									
	4) Medical necessity authorization issues									
	5) Statistical data trending and tracking issues									
DI.6b	Staff are knowledgeable about and carry out their responsibilities for providing products and services in accordance with reimbursement and regulatory guidelines.									
DI.7	The Pharmacy Organization contributes to the development and expansion of knowledge in Pharmacy practice, as appropriate.									
DI.7a	A Pharmacy Organization participating in research or investigative studies ensures that clients are fully informed and provide written consent.									
DI.7b	Arrangements for student education experiences are formalized in written contracts or agreements that specify the responsibilities of the Pharmacy organization and the educational institution									
DI.7c	The Pharmacy organization demonstrates a positive attitude regarding research initiatives and considers requests for research in the area of pharmaceutical practice as appropriate.									
DI.7d	The Pharmacy organization encourages the publication of significant outcomes related to the management and practice of pharmacy.									

EVIDENCE GUIDELINES	CITATION STATEMENTS
D = Documentation S = Survey O = Observation I = Interview	
D: Current Public Disclosure policy includes the element of DII.1a, if applicable, in addition to the elements of CII.1a. (DII.1a)	
D: The Client Bill of Rights statement and/or other admission documents includes elements of DII.1b in addition to the elements of CII.1b . (DII.1b)	
D: Record review confirms that the Client Bill of Rights is signed by the client or client representative and is filed in the record. (DII.1c)	
O: Observation of the open door pharmacy validates that the Client Bill of Rights is posted in a public area. (DII.1d)	
D: Record review validates that pharmacy products and services are provided to clients consistent with the organization's stated scope of service. (DII.1e)	

	PHARMACY STANDARDS	Prior Visit NM	SS	Current Visit						COMMENTS
				NA	Met	Com	NM	RA	Rec	
UP II	QUALITY OF SERVICES									
DII.1	The Scope of Services drives the activities of the Pharmacy Organization and ensures public disclosure, client rights, and ethical standards of business and clinical practice.									
DII.1a	The written public disclosure policy makes the Annual Report for Corporations, if applicable, available to the public on request.									
DII.1b	A written Client Bill of Rights statement or other written admission documents are provided to the client or the client's representative at the start of care or at the time of initiation of care and include the right to be fully informed of:									
	1) Services and products being provided									
	2) Organization's ownership and control									
	3) Names and qualifications of individuals providing products and services									
	And the right to:									
	4) Participate in one's own care									
	5) Continuity of products and services									
	6) Education about the products and services to be provided									
	7) Refuse part or all of the products and services to be provided									
	8) Receive products and services in a timely manner and in accordance with organizational policy									
	9) Be referred to another organization									
	10) Be free from abuse or exploitation of any kind									
	11) Receive information, both verbal and written, in an understandable format.									
DII.1c	The Client Bill of Rights is signed by the client or a representative of the client and made a permanent part of the client's record.									
DII.1d	For clients receiving open door pharmacy services, the Client Bill of Rights is posted in a public area accessible to those clients.									
DII.1e	The Pharmacy organization's products and services are provided in accordance with the organization's scope of services.									

EVIDENCE GUIDELINES	CITATION STATEMENTS
D = Documentation S = Survey O = Observation I = Interview D: Record review validates that pharmacy products and services are provided to clients consistent with the organization's stated scope of service. (DII.1e) I & O: Interview and observation of practice confirms that the pharmacy organization is providing services as defined in DII.2a. D: Job descriptions and/or other policies identify duties and responsibilities of each discipline, which are consistent with national practice standards. (DII.2b) I & O: Interviews and direct observation of staff in practice confirm staff understanding and fulfillment of responsibilities. (DII.2b) D: Clinical record documentation by respective disciplines verifies fulfillment of assigned responsibilities. (DII.2b)	

	PHARMACY STANDARDS	Prior Visit NM	SS	Current Visit						COMMENTS
				NA	Met	Com	NM	RA	Rec	
	1) Statistical reports confirm that products and services are provided consistent with the Pharmacy organization's scope of services.									
	2) Staff at all levels are knowledgeable about and support the Pharmacy organization's mission and scope of services.									
DII.2	Pharmacy services are provided in accordance with organizational policies and procedures, to clients in their place of residence, and may include dispensing at the pharmacy site, transported delivery to home/client site or mailed delivery.									
DII.2a	Pharmacy services include but are not limited to:									
	1) Interpretation and evaluation of the prescription order									
	2) Drug product selection, compounding, dispensing, storage									
	3) Distribution of drugs and devices									
	4) Advising the prescriber and other health care professionals, the clients and/or caregiver as to therapeutic actions, utilization and possible adverse reactions and interactions in order to encourage a positive client outcome.									
DII.2b	Pharmacy services are provided by or under the direction and supervision of a qualified pharmacist.									
	1) Professional pharmacy service is provided by a registered pharmacist and include:									
	(a) Overseeing the drug control system including:									
	1) Receipt of prescription drugs and prescription orders									
	2) Storage of medications									
	3) Packaging of medications									
	4) Preparation and dispensing of prescriptions									
	5) Labeling									
	6) Preparation of prescriptions for delivery									
	(b) Instruction/counseling clients and caregivers regarding the specific drug therapy including possible adverse reactions and/or interactions									

EVIDENCE GUIDELINES	CITATION STATEMENTS
D = Documentation S = Survey O = Observation I = Interview	
D: Job descriptions and/or other policies identify duties and responsibilities of each discipline, which are consistent with national practice standards. (DII.2b)	
I & O: Interviews and direct observation of staff in practice confirm staff understanding and fulfillment of responsibilities. (DII.2b)	
D: Clinical record documentation by respective disciplines verifies fulfillment of assigned responsibilities. (DII.2b)	
I: Procedures for ensuring availability of drugs, supplies and equipment are described. (DII.2c)	
I: Job descriptions and/or policies include the indicated delivery personnel responsibilities. (DII.2d)	
I & O: Interviews and direct observation of delivery services during home visits confirms staff understanding and fulfillment of responsibilities. (DII.2d)	
I: Clients relate satisfaction with delivery services. (DII.2d)	

	PHARMACY STANDARDS	Prior Visit NM	SS	Current Visit						COMMENTS
				NA	Met	Com	NM	RA	Rec	
	(c) Providing information regarding the safe and appropriate use of medications to other health care professional									
	(d) Identifying appropriate outcomes of drug therapy									
	(e) Consulting on drug therapy and coordinating with other health care professionals									
	(f) Monitoring and documenting ongoing drug therapy including the assessment of:									
	1) The therapeutic appropriateness of the choice of drug(s)									
	2) Therapeutic duplication in the client's drug routine									
	3) Appropriateness of the dose, frequency and route of administration									
	4) Adherence to drug regimen									
	5) Potential drug, food or diagnostic test interactions of disease limitations to drug use									
	6) Laboratory or clinical monitoring methods to detect drug effectiveness, side effects, toxicity or adverse effects									
	7) Preparing and maintaining clinical records									
	(g) Prescribing activities consistent with state/federal regulations.									
	2) Pharmacy technical services are provided by pharmacy technicians who have been trained for all tasks performed in compliance with state law, job description and organizational policy.									
DII.2c	The Pharmacy Program provides pharmaceutical care, related supplies and equipment to clients.									
DII.2d	Delivery services are provided directly or by arrangement in compliance with laws and regulations and include:									
	1) Safe and clean transport of pharmaceuticals and supplies to and from client homes/designated sites.									
	2) Timely delivery of pharmaceuticals and supplies									
	3) Record keeping									
	4) Setting up equipment in client homes, if applicable									

EVIDENCE GUIDELINES	CITATION STATEMENTS
D = Documentation S = Survey O = Observation I = Interview	
I: Procedures for ensuring availability of drugs, supplies and infusion devices when not available from the organization are described. (DII.2e, DII.2f)	
I: Staff describe how necessary services (pharmacy and delivery) are made available to clients at all times (on-call practices). (DII.3a)	
D: Review of documents (complaint log, client satisfaction survey, on-call logs) validate that response times are consistent with policies and meet client needs. (DII.3a)	
D & I: An on-call plan is available, and staff describe the on-call plan. (DII.3b)	
O: Testing of the on-call plan validates that the organization is in compliance with its on-call coverage plan and policy. (DII.3b)	
I: Client/family describes service availability after hours. (DII.3c)	
D: Written contingency plan protocols are available and include items 1 – 3. (DII.3d)	
D: Written policy identifies admission criteria and referral process, including when the organization does not provide the needed product or service. (DII.4a)	
D: Policies and procedures define the responsibilities of the pharmacists, and record review confirms documentation by the pharmacist. (DII.4b)	
O: Observation validates assumption/ fulfillment of responsibilities. (DII.4b)	
D: Policies and/or procedures define the responsibilities for service coordination. (DII.4c, DII.4d)	

	PHARMACY STANDARDS	Prior Visit NM	SS	Current Visit						COMMENTS
				NA	Met	Com	NM	RA	Rec	
DII.2e	The organization has a process in place for assuring the availability of drug and supplies to clients in their designated sites not available from the organization.									
DII.2f	The organization has a process in place for assuring the provision of infusion devices to clients in their homes/designated sites when not available from the organization.									
DII.3	Clinical services and products are accessible and available to clients on an emergency basis 24 hours a day, 7 days a week.									
DII.3a	The Pharmacy Organization is accessible and responsive to the needs of Clients during normal work hours and after hours which includes:									
	1) Timely telephone response									
	2) Timely on-site response, if indicated									
	3) Product and service delivery prior to scheduled use									
DII.3b	There is a plan for on-call coverage for after hours, weekends and holidays.									
DII.3c	Clients are informed of the process for accessing service during normal work hours and after hours.									
DII.3d	Written contingency plans delineate protocols for prioritizing delivery of product and services to clients including:									
	1) Disaster preparedness									
	2) Inclement weather events									
	3) Unexpected critical staffing deficits									
DII.4	The Pharmacy Organization admits clients whose service needs can be met and ensures continuity of care/service through coordination of client services.									
DII.4a	Clients are admitted to service and continued on service, based on the reasonable expectation that their needs can adequately and safely be met by the program.									
DII.4b	A pharmacist assumes responsibility for planning, implementing therapy, evaluating the outcomes of therapy provided as applicable and documenting in the client record.									
DII.4c	Care is coordinated for each client by the pharmacist and includes at a minimum:									

EVIDENCE GUIDELINES	CITATION STATEMENTS
D = Documentation S = Survey O = Observation I = Interview	
D: Policies and/or procedures define the responsibilities for service coordination. (DII.4c, DII.4d)	
D: Review of records confirms that care coordination activities are performed. (DII.4c, DII.4d)	
Note: Appropriate referrals involves referrals for additional services as indicated. (DII.4d.4)	
D: Client records document interdisciplinary coordination as appropriate. (DII.4e)	
I & O: Pharmacists indicate how drug profile information is made accessible to other appropriate professionals, the mechanisms for coordination, the procedures for coordinating delivery of medications, equipment and supplies and that that they are delivered and available as appropriate. (DII.4e)	
D: Client assessment policies and record review validate the inclusion of specified items for all pharmacies. (DII.5a)	

	PHARMACY STANDARDS	Prior Visit NM	SS	Current Visit						COMMENTS
				NA	Met	Com	NM	RA	Rec	
	1) Periodic verbal, telephone or electronic communication with other professionals involved in the care of the client									
	2) Timely documentation of the coordination of care activities									
	3) Involvement of the client/client representative when indicated									
DII.4d	For other than open door pharmacies, care coordination includes elements 1-3 of DII.4c plus the following additional components:									
	1) Initial assessment of the client, family and, if applicable, the home environment									
	2) Development of a plan of care									
	3) Determination of expected outcomes									
	4) Appropriate referral and follow up									
	5) Implementation of the care plan									
	6) Ongoing evaluation									
	7) Plan of termination of care									
DII.4e	The pharmacist works collaboratively with other health care professionals to assure coordination of care.									
	1) The client drug profile information is available to professionals participating in the care of the client:									
	a) at a minimum, during operating hours for all pharmacies									
	b) at all times, including after hours for infusion pharmacies									
	2) The delivery of medications, equipment, and supplies is coordinated with other professionals involved with the care of the client to ensure that proper products and supplies are available when needed.									
DII.5	**The Pharmacy Organization defines the plan of care process, including assessments, physician oversight, dispensing and client training.**									
DII.5a	An initial client assessment is made by the pharmacist prior to dispensing which includes at a minimum:									
	1) Name, address, telephone number, gender, age/date of birth of client									
	2) Allergies/sensitivities of client									
	3) Medication Order									
	4) Physician name, telephone number									

EVIDENCE GUIDELINES	CITATION STATEMENTS
D = Documentation S = Survey O = Observation I = Interview	
D: Client assessment policies and record review validate the inclusion of specified items in DII.5a and DII.5b for infusion and long term care pharmacies. (DII.5b)	
D: Medication assessment policy and record review validate the inclusion of elements 1-6. (DII.5c)	
D, I &O: Interview, observation and record review confirm that client assessments and medication assessments are conducted prior to dispensing. (DII.5a,DII.5b,DII.5c)	
D: Policies establish mechanisms for obtaining written physician verification of and approval for verbal orders. (DII.5d)	
D: Record review documents that required prescriptions were received prior to dispensing medications. (DII.5d)	
D: Record review documents that verbal orders are taken and signed by the pharmacist prior to filling orders. (DII.5d)	
D: Written policy is available and includes elements 1-11. (DII.5e)	
O: Drug labels include the indicated items. (DII.5e)	

	PHARMACY STANDARDS	Prior Visit NM	SS	Current Visit						COMMENTS
				NA	Met	Com	NM	RA	Rec	
DII.5b	For infusion and long term care pharmacies, an initial client assessment is made by the pharmacist prior to dispensing which includes elements 1-4 of DII.5a plus the following additional components as appropriate:									
	1) Chief Complaint/Medical history/Diagnosis									
	2) Height and weight of client									
	3) Client Infection, Sensitivities obtained as available									
	4) Significant Lab Results									
DII.5c	A medication assessment is made by the pharmacist prior to dispensing which includes at a minimum:									
	1) Potential drug interaction									
	2) Potential for poly-pharmacy									
	3) Appropriate dose and frequency									
	4) Appropriate time of administration									
	5) Appropriate route and method of administration									
	6) Appropriate infusion device of administration, if applicable									
DII.5d	Pharmaceuticals are dispensed according to the prescription of a physician or physician designee legally authorized to prescribe in compliance with state regulation:									
	1) Written, verbal or faxed prescriptions are available to the pharmacist before dispensing the medication									
	2) Verbal orders taken from a physician or physician designee are recorded and signed by the pharmacist prior to filling the medication order									
DII.5e	All pharmaceutical products dispensed to clients are appropriately labeled according to state and federal regulations and, at a minimum, include:									
	1) Name, address and telephone number of the pharmacy									
	2) Date the prescription was dispensed									
	3) Expiration date of the medication									
	4) Pharmacy's prescription number									
	5) Client's full name									
	6) Name of the drug, brand, strength, if applicable, and the amount dispensed									
	7) Directions for use									
	8) Prescriber's name									
	9) Other pertinent information or cautionary labels									

EVIDENCE GUIDELINES	CITATION STATEMENTS
D = Documentation S = Survey O = Observation I = Interview	
D: Plans of care are available for each client and include items 1-6. (DII.5f) *Note: Review by physician may include review of orders, copies of plans of care mailed/faxed to physician. (DII.5f.6)*	
D: Written policy and procedure define the process for confirming client identification. (DII.5g)	
I & O: Pharmacy and delivery staff explain the process for confirming client identification prior to dispensing. (DII.5g)	
D: Policies and procedures with specifications detailed are available for emergencies for pharmacy infusion services. (DII.5h)	
I: Staff are familiar with emergency procedures and provide examples of their appropriate use. (DII.5h)	
D: Drug information and instructional materials are prepared for all types of products and services provided. (DII.5i)	
D: Review of documents validates that the client or caregiver was instructed in self-administration of therapy when self-administration was indicated. (DII.5j)	
D: Client training/education is documented. (DII.5i, DII.5j)	
I & O: Clients understand their regimes. (DII.5i, DII.5j)	
D: Client records document that appropriate clinical services were provided to clients. (DII.6a)	
D: Client records are current and include elements 1-4 . (DII.6a)	
D: Client records document adherence to all clinical written policies and procedures. (DII.6a)	
D: Client drug profiles are current and include elements a– h. (DII.6a.1)	

	PHARMACY STANDARDS	Prior Visit NM	SS	Current Visit						COMMENTS
				NA	Met	Com	NM	RA	Rec	
	10) Rate, route and method of administration									
	11) For IV mixture drugs, rate of administration and expiration date of the fluid									
DII.5f	A comprehensive plan of care is developed by infusion pharmacies which includes:									
	1) Establishment of Therapy Specific Goals									
	2) Determination of Expected Outcomes									
	3) Determination of Educational Needs									
	4) Establishment of Monitoring Plan									
	5) Determination of Achievement of Goals/Outcomes									
	6) Periodic Review by Prescribing Physician									
DII.5g	Client identification is confirmed prior to dispensing.									
DII.5h	For pharmacy infusion services, there are policies and procedures for emergency situations including, ordering of emergency kits with appropriate drugs by the physician and placement of these kits in the client's home, where appropriate.									
DII.5i	Drug information and instructional materials for administration are provided to the client or client caregiver at the time of dispensing.									
DII.5j	Client training/education in self-administration is provided upon initiation of therapy, as applicable									
DII.6	Client records are maintained for each client and are utilized as a tool for coordination of services, as legal documentation of products and services provided and as a basis for billing and reimbursement procedures.									
DII.6a	Adequate and appropriate pharmacy records are maintained									
	1) Drug profiles are maintained for all clients and include the following information:									
	(a) Name, gender, birth date and weight (when appropriate)									
	(b) Address and client identification									
	(c) Allergies or sensitivities									
	(d) Diagnosis									
	(e) Current drug regimen									
	(f) Dosages									
	(g) Relevant clinical information regarding drug therapy									
	(h) Physician's name									

EVIDENCE GUIDELINES	CITATION STATEMENTS
D = Documentation S = Survey O = Observation I = Interview	
D: Pharmacy dispensing records include elements a-k. (DII.6a.2)	
D Records document adherence to first dose policy for new drug therapies. (DII.6a.2)	
D: Pharmacy dispensing records for other than open door pharmacies include items a-k of DII.6a.2 and elements a-d of DII.6a.3. (DII.6a.3)	
Note: Compounding instructions may be found in protocols, policies and/or specific instructional forms. (DII.6a.3c)	
Note: Documentation exists that a pharmacist oversees the process for dispensing, i.e., Pharmacist signature/initials on the label, on the compounding sheet, etc. (DII.6a.3d)	
D: Narcotic records include items specified. (DII.6a.4)	
I & O: Controlled substance records are maintained in compliance with state, federal and practice regulations. (DII.6a.4)	
D: Policy is current and describes signature authentication. (DII.6b)	
I: Records/system administrator describes the inclusion of the 9 items in the ongoing process of ensuring protection of data. (DII.6b)	
O: Pharmacy staff protect data consistent with policy and state law. (DII.6b)	
I & O: A back-up and storage system is in place. (DII.6b)	

	PHARMACY STANDARDS	Prior Visit NM	SS	Current Visit						COMMENTS
				NA	Met	Com	NM	RA	Rec	
	2) Dispensing records are maintained for pharmaceuticals which include:									
	(a) Client's identification, name and address									
	(b) Name of medication									
	(c) Strength and dosage form									
	(d) Quantity dispensed									
	(e) Physicians' name									
	(f) Dispensing pharmacist/technician identification									
	(g) Prescription number									
	(h) Date dispensed									
	(i) Directions for use									
	(j) Expiration date									
	(k) Number of refills authorized									
	3) Dispensing records for other than open door pharmacies are maintained for pharmaceuticals which include elements a-k of DII.6a2 plus the following:									
	(a) Lot number(s) of drugs									
	(b) Date of the addition(s) to intravenous admixture drugs									
	(c) Special compounding instructions as applicable									
	(d) Documentation of verification procedures									
	4) Controlled substance records are maintained in accordance with state, federal and practice regulations documenting that:									
	(a) A controlled substance inventory is performed in compliance with state or federal regulation.									
	(b) The pharmacist in charge is held accountable for the exact count of Schedule II pharmaceuticals									
	(c) The pharmacist in charge is held accountable for an approximate count of Schedule III, IV, and V pharmaceuticals.									
DII.6b	Automated clinical record systems ensure consistent and ongoing protection of data.									
	1) Written policy describes signature authentication in accordance with individual state law									
	2) Safeguards prevent unauthorized access to inputted information									
	3) Individual and protected access codes are assigned to individuals designated to perform data entry									
	4) Automated programs designate and control areas of access by authorized personnel based on a personal identifier and position in the organization									

EVIDENCE GUIDELINES	CITATION STATEMENTS
D = Documentation S = Survey O = Observation I = Interview	
I: Records/system administrator describes the inclusion of the 9 items in the ongoing process of ensuring protection of data. (DII.6b)	
I: The Pharmacy Director describes the performance improvement process for the pharmacy program. (DII.7a)	
D: Evidence exists of utilization of performance improvement findings to resolve problems and improve quality of service/ products. (DII.7a)	
D: The performance improvement program includes items specified in DII.7a.	
D: The performance improvement plan includes items specified in DII.7b.	
D: Evidence exists of monitoring and analysis of findings as specified in DII.7c.	
I: Pharmacy Director and staff describe use of findings to identify problems and to improve performance. (DII.7c)	
D: Staff orientation and in-service programs validate discussion of improvement program and indicators. (DII.7d)	

	PHARMACY STANDARDS	Prior Visit NM	SS	Current Visit						COMMENTS
				NA	Met	Com	NM	RA	Rec	
	5) The computer's internal clock designates date and time of entries									
	6) Automated controls prevent a change in entry, allowing only corrections									
	7) Hardcopies of automated data are retrievable by designated personnel									
	8) A system for validation of inputted data is in place									
	9) An automated system for backup and storage of data is controlled, and the data is stored in a safe environmental place.									
DII.7	The adequacy, appropriateness, effectiveness and outcomes of products, services and supplies provided are routinely assessed.									
DII.7a	The Pharmacy Program has a formalized quality improvement program which is designed to:									
	1) Identify desired outcomes									
	2) Identify strategic and at-risk activities									
	3) Establish monitoring parameters for these activities									
	4) Establish minimal standards or criteria to be met									
	5) Describe methods used to improve the quality of service and to achieve the desired outcomes.									
DII.7b	The Pharmacy Program has a written performance improvement plan which includes:									
	1) Description of specific monitoring and evaluation activities									
	2) Specification of how results are to be reported and evaluated									
	3) Identification of appropriate follow-up mechanisms when thresholds are exceeded									
	4) Delineation of individual responsibilities for each aspect of the program.									
DII.7c	The Pharmacy Program's performance improvement program includes but is not limited to:									
	1) Monitoring for medication errors									
	2) Monitoring and analysis of the findings from surface testing, environmental air sampling and end product testing that includes sterility and pyrogens.									
DII.7d	Staff orientation and in-service programs integrate a focus on quality.									

EVIDENCE GUIDELINES	CITATION STATEMENTS
D = Documentation S = Survey O = Observation I = Interview	
D & I: When the pharmacy is part of a larger organization, evidence is provided demonstrating integration of quality improvement plans. (DII.7e)	
D: Written policies exist and include items 1-10. (DII.8a)	
O: Observation of staff performing responsibilities confirms that staff adhere to infection control and safety policies and procedures. (DII.8a)	
D: Record review confirms that home environment assessments were conducted when indicated and that safety hazards were identified and precautionary instructions were provided to the client and documented. (DII.8b)	
D: Policy specifies types of staff designated to dispose of controlled substances. (DII.8c.1)	
D: Records confirm adherence to policy. (DII.8c.1)	
D: A Material Safety Data Sheet clearly outlines protocols for disposal of hazardous products. (DII.8c.2)	
O: The Material Safety Data Sheet is available in the pharmacy. (DII.8c.2) *Note: The Material Safety Data Sheet information may be available on the pharmacy website as long as each pharmacy employee has access to the information.*	

	PHARMACY STANDARDS	Prior Visit NM	SS	Current Visit						COMMENTS
				NA	Met	Com	NM	RA	Rec	
DII.7e	The Pharmacy Program's performance improvement plan is integrated into the overall organizational quality improvement plan, as applicable.									
DII.8	The health and well being of employees and clients is promoted and maintained through education and implementation of current infection control policies and safety measures.									
DII.8a	Infection control and safety measures for the preparation, dispensing and disposal of pharmaceuticals include but are not limited to:									
	1) Observation of standard precautions									
	2) Adequate hand hygiene/hand washing									
	3) Procedures for preventing exposure to blood borne pathogens									
	4) Glove, gown and eye shield use while compounding hazardous products and chemotherapeutic substances									
	5) Use of aseptic technique									
	6) Appropriate use of particulate and/or bacterial filtration									
	7) Hood decontamination practices									
	8) Venting of the laminar flow hood outside the building or use of a Class II Biological Safety Cabinet when compounding cytotoxic drugs									
	9) Proper disposal of needles used in the preparation of pharmaceuticals done by disposing of needles in a tamper proof, puncture resistant container									
	10) Proper disposal for hazardous waste products									
DII.8b	When applicable, the home environment is assessed to evaluate potential safety hazards and to instruct the client and/or those associated with the care of the client about safety precautions. The assessment and client teaching is documented in the client's record.									
DII.8c	Disposal of outdated drugs, controlled substances or hazardous wastes is documented and conforms to state and federal requirements.									
	1) Controlled substances are returned to the Drug Enforcement Administration if required. Documentation of the disposal of controlled substances on site is witnessed by two individuals and includes the amount and type of the drug.									

EVIDENCE GUIDELINES	CITATION STATEMENTS
D = Documentation S = Survey O = Observation I = Interview	
D: A Material Safety Data Sheet clearly outlines protocols for disposal of hazardous products. (DII.8c.2)	
O: The Material Safety Data Sheet is available in the pharmacy. (DII.8c.2) *Note: The Material Safety Data Sheet information may be available on the pharmacy website as long as each pharmacy employee has access to the information.*	
D: Written instructions regarding disposition of hazardous substances in homes are provided to appropriate clients. (DII.8c.3)	
I: Staff and client are aware of disposition procedures for hazardous substances, if indicated. (DII.8c.3)	
D. Records confirm adherence to policy and regulation. (DII.8c.4)	
D: Client instructions regarding preparation of sterile solutions, storage methods, and durations are documented. (DII.8d)	
I: Clients preparing sterile solutions at home are able to describe appropriate preparation and storage precautions. (DII.8d)	
D: Written infection control and safety policies for equipment/delivery service are available. (DII.8e)	
D: Policies specify maintenance, testing, and repair specifications for each type of equipment. (DII.8e)	
I & O: Equipment is maintained, tested, and repaired according to manufacturer's recommendations. (DII.8e)	
I & O: Staff demonstrate an understanding of infection control procedures and policies. (DII.8f)	
D: Policies specify elements 1 – 5 of DII.8f. (DII.8f)	
D & O: Review of records and observation of practice confirms adherence to organizational policies and that activities are conducted on a routine basis. (DII.8f)	

	PHARMACY STANDARDS	Prior Visit NM	SS	Current Visit						COMMENTS
				NA	Met	Com	NM	RA	Rec	
	2) Material Safety Data Information is kept in the pharmacy and identifies procedures for disposal of hazardous products									
	3) Clients are instructed regarding the proper disposal of hazardous products in the home									
	4) Records are maintained, as required									
DII.8d	When clients and caregivers prepare sterile preparations in the home, they are instructed verbally and in writing regarding safeguards against microbial contamination, including, but not limited to the following:									
	1) Instructions regarding the preparation of the sterile solution									
	2) Storage methods									
	3) Duration and stability of the prepared solution									
DII.8e	Infection control and safety control policies are established and implemented for the equipment/delivery service, including:									
	1) Maintenance, testing and repair of equipment according to manufacturer's guidelines									
	2) Cleaning and storage of reusable equipment between usage									
	3) Inspection of equipment prior to delivery.									
DII.8f	The Pharmacy Program that prepares compounded sterile products conducts the following activities on a routine basis:									
	1) Routine disinfection and quality testing of direct compounding environment									
	2) Visual confirmation of personnel processes regarding gowning, and other infection control/safety measures									
	3) Review of orders and packages of ingredients to assure correct identity and amounts of ingredients									
	4) Visual inspection of compounding sterile products									
	5) Media-fill test procedure performed at least annually for each person									
DII.9	Client complaints and concerns are responded to and resolved in a timely manner.									
DII.9a	The complaint process includes:									

EVIDENCE GUIDELINES	CITATION STATEMENTS
D = Documentation S = Survey O = Observation I = Interview D: Documentation validates that the complaint process includes elements 1-9. (DII.9a) D: Review of complaint log validates that complaints have been responded to consistent with the organization's policy and process. (DII.9a)	

	PHARMACY STANDARDS	Prior Visit NM	SS	Current Visit						COMMENTS
				NA	Met	Com	NM	RA	Rec	
	1) Designation of the individual(s) responsible for responding to the complaint									
	2) Procedures for responding to complaints									
	3) Time frame for responding to complaints									
	4) Assurance that corrective action is taken as appropriate									
	5) Assurance that client and family rights are protected									
	6) Follow-up activities									
	7) Resolution of the complaint									
	8) Complainant is informed of the outcome									
	9) Trending of justified complaints									

EVIDENCE GUIDELINES	CITATION STATEMENTS
D = Documentation S = Survey O = Observation I = Interview	
D: Staffing assignments are available. (DIII.1a)	
I: Mechanisms for evaluating workload demands are described. (DIII.1a)	
I: Mechanisms for employee selection are described. (DIII.1b)	
D: Documentation of required elements 1-10 validates compliance and inclusion in the personnel files, health files, or the administration files. (DIII.1b)	
D: Records include diplomas/ transcripts, current licenses and continuing education attendance (if required) for all clinical/ professional staff. (DIII.1b.3,4,5)	
D: Documentation of certification or adequate training is available for pharmacy technicians and delivery personnel identifying training provided for all tasks performed by the technician and the driving personnel. (DIII.1b.6, 8)	
I: Delivery and equipment service personnel selection process is described, including driving record checks, and compliance with relevant motor carrier safety regulations. (DIII.1b.7)	
I: Mechanisms for assessing and updating clinical competencies/ skills are described. (DIII.1c)	
D: Documentation of clinical competency/skill assessment at time of hire and annually thereafter is available. (DIII.1c)	

	PHARMACY STANDARDS	Prior Visit NM	SS	Current Visit						COMMENTS
				NA	Met	Com	NM	RA	Rec	
DIII	**ADEQUATE RESOURCES - HUMAN, FINANCIAL & PHYSICAL**									
DIII.1	**The Pharmacy organization has adequate and appropriate human resources to meet workload demands.**									
DIII.1a	Staffing guidelines are developed and implemented to adequately meet workload demand.									
DIII.1b	Qualified personnel are recruited and retained. Documentation is found in the personnel files, health files or administration files of the following:									
	1) Budgets allocate sufficient funds to ensure staffing at all levels and are maintained to adequately meet workload demands									
	2) Positions, new and vacant, are filled on a timely basis to sustain organizational performance goals									
	3) Clinical staff show evidence of graduation from colleges approved or accredited by their respective professional organization									
	4) Clinical staff maintain and show evidence of current licensure									
	5) Clinical staff show evidence of continuing education when required									
	6) Pharmacy technicians show evidence of certification, or have evidence of adequate training, for all tasks performed in conformance with applicable laws									
	7) Delivery personnel, when utilized, have a clean driving record and maintain a current driver's license									
	8) Delivery personnel, when utilized, show evidence of adequate training for all tasks performed									
	9) Professional & technical personnel show evidence that professional skills are assessed and updated									
	10) Compounding personnel show evidence of skills, training, and competency testing to perform and document compounding duties.									
DIII.1c	Clinical competency evaluations are performed to assess employee basic skill levels for all staff providing client care/services:									
	1) At time of hire									
	2) Annually, thereafter									

EVIDENCE GUIDELINES	CITATION STATEMENTS
D = Documentation S = Survey O = Observation I = Interview	
D: Documentation of clinical competency assessment including elements 1-5 at time of hire and annually thereafter is available. (DIII.1d)	
I: Mechanism for assessing clinical competency is described by manger and pharmacy personnel. (DIII.1d)	
D: An orientation plan is available and includes elements 1-5. (DIII.1e)	
D & I: There is an appropriate supervision plan for all levels of staff and each employee. (DIII.1f)	
D: Records show documentation of state/organizational required in-service attendance by pharmacists. (DIII.1g) *Note: In-services may be provided by the organization or other approved entities.*	
D: Records show documentation of organization's provision of annual in-service/continuing education program and pharmacist's attendance at the in-service/ continuing education session. (DIII.1h)	
I: Pharmacy Director describes mechanism for assuring compliance with responsibilities. (DIII.2)	

	PHARMACY STANDARDS	Prior Visit NM	SS	Current Visit						COMMENTS
				NA	Met	Com	NM	RA	Rec	
DIII.1d	Clinical competency evaluations of pharmacy personnel who use laminar flow hoods and/or Class II Biological safety cabinets are conducted at time of hire and annually thereafter and include at a minimum:									
	1) Written test to verify employee's understanding of the concepts of aseptic technique									
	2) Observation of employee's aseptic technique									
	3) Sterility validation testing for all employees who make sterile products									
	4) Observation of cleaning, testing and calibration of infusion equipment									
	5) Observation of cleaning, testing and calibration of compounding equipment									
DIII.1e	The orientation plan addresses at a minimum:									
	1) Mission statement									
	2) Organizational Chart									
	3) Lines of authority and responsibility									
	4) Job related responsibilities (job description)									
	5) Human Resources policies/conditions of employment									
DIII.1f	There is adequate supervision of all pharmacy personnel.									
	1) Professional Pharmacy services are provided by or under the direction and supervision of a qualified Pharmacist.									
	2) Staffing ratios of pharmacists to pharmacy technicians are in compliance with state regulations.									
DIII.1g	Pharmacists show evidence of participation in formal in-service programs required by state regulation and organization policy.									
DIII.1h	The organization provides a minimum of one medication safety in-service annually									
DIII.2	Formal written contracts and agreements with other organizations and/or individuals for the provision of pharmacy products and services to pharmacy organization clients detail specific responsibilities of the parties involved.									

EVIDENCE GUIDELINES	CITATION STATEMENTS
D = Documentation S = Survey O = Observation I = Interview D: Contracts for pharmacy services contain all elements in CIII.2a-b, DIII.2a and DIII.2b. (DIII.2a, DIII.2b) I: Pharmacy Director describes mechanism for assuring compliance with responsibilities. (DIII.2)	

	PHARMACY STANDARDS	Prior Visit NM	SS	Current Visit						COMMENTS
				NA	Met	Com	NM	RA	Rec	
DIII.2a	Formal written contracts and agreements with other organizations and/or individuals for provision of pharmacy services includes specific responsibilities as defined in CIII.2a-b and, in addition, the following specific responsibilities:									
	1) Which organization has the authority to accept and terminate client services									
	2) Services provided under contract must be in compliance with professional standards									
	3) The manner, in which products and services will be controlled, coordinated and evaluated									
	4) Designation of responsibilities for orientation									
DIII.2b	Pharmacy services when provided under arrangement are in accordance with CHAP Pharmacy Standards and are in compliance with CIII.2a-b, DIII.2a and, in addition, include the provisions for:									
	1) Who is responsible for teaching the client about pharmaceuticals									
	2) Assurance that personnel meet the pharmacy program's educational and training requirements									
	3) Maintenance of current licensure and certification where required									
	4) On site supervision of pharmacy personnel									
	5) Hours when pharmaceutical services are available to the client, including arrangements for services during "off hours"									
	6) Time frames for response to new referrals									
	7) Responsibilities of contractor and contractee, including:									
	(a) Who assesses the need for pharmaceuticals									
	(b) Who contacts the pharmacy									
	(c) Who obtains the written physician orders									
	(d) Who generates drug profiles and to whom they will be made available of those involved with the client's care									
	(e) Who maintains records for investigational drugs and controlled substances									

EVIDENCE GUIDELINES	CITATION STATEMENTS
D = Documentation S = Survey O = Observation I = Interview	
D: Contracts for delivery services contain all elements in CIII.2a-b, DIII.2a and DIII.2c. (DIII.2c)	
D: Policies pertaining to cash management and contingency planning are available. (DIII.3a)	
I: Pharmacy Director describes how the organization manages its cash and cites examples of contingency planning. (DIII.3a)	
D&I: Pharmacy Director and/or Financial Manager describe and document the insurance coverage and discuss the rationale for the amounts. (DIII.3b)	
D: New Pharmacy product/service plan proposals include specified elements. (DIII.3c)	
I: Management team describes examples of recognition of inter-relationship of finance, quality, product and service operations. (DIII.3d)	
O: Observation of the physical facility validates that elements 1 -7 are in evidence and in conformance with state/federal requirements. (DIII.4a)	

	PHARMACY STANDARDS	Prior Visit NM	SS	Current Visit						COMMENTS
				NA	Met	Com	NM	RA	Rec	
	(f) _ Procedure to follow assuring the availability of drugs and supplies to the clients in their home when not available from the pharmacy									
	(g) Mechanisms for evaluating the contracted service									
DIII.2c	Delivery of products and supplies when provided to clients under arrangement are in compliance with CIII.2 a-b, DIII.2a and, in addition, include the provisions for:									
	1) Ensuring clean and safe transport of equipment and supplies									
	2) Timely delivery of products and supplies									
	3) Setting up equipment in client's homes, where appropriate									
	4) Adequately trained delivery personnel									
	5) Client education, where appropriate									
	6) Appropriate documentation									
DIII.3	**The Pharmacy Organization/Program has adequate and appropriate financial resources to meet its stated mission.**									
DIII.3a	The organization has a contingency plan and/or policies and procedures to adequately address cash or operating short falls that may impact the products and services it provides.									
DIII.3b	Insurance coverage is maintained for the loss due to general liability, product liability, professional liability and work related injuries.									
DIII.3c	New program, product or service planning and development occurs prior to implementation which includes analysis of effectiveness and profitability of the project.									
DIII.3d	The management team's performance reflects an understanding of the interrelationship of finances, quality, product and service operations and long term viability of the organization.									
DIII.4	**The Pharmacy organization has adequate and appropriate physical facilities to accomplish its stated mission.**									
DIII.4a	The Pharmacy organization has the necessary space, equipment and supplies for safe preparation, dispensing, storage and delivery of pharmaceuticals in compliance with state and federal requirements, and includes at a minimum:									

EVIDENCE GUIDELINES	CITATION STATEMENTS
D = Documentation S = Survey O = Observation I = Interview	
D: Written policies specify elements 1-5. (DIII.4b)	
O: Work surfaces and equipment are cleaned and disinfected in compliance with pharmacy policy. (DIII.4b)	
Note: Compounding environment includes walls and floors. (DIII.4b.2)	
D,I&O: Interview, observation and review of reference data validate that professional/community standards of practice are followed. (DIII.4c)	
O: Observation validates that sterile and non-sterile preparation areas are separate and adequate. (DIII.4d)	

	PHARMACY STANDARDS	Prior Visit NM	SS	Current Visit						COMMENTS
				NA	Met	Com	NM	RA	Rec	
	1) Designated area for preparation of sterile products for dispensing									
	2) Hot and cold running water with sink									
	3) Walls, ceilings and floors made of non-porous cleanable surfaces									
	4) Accurate balance and measuring devices									
	5) Adequate ventilation and lighting									
	6) Disposable hand drying towels									
	7) Adequate storage facilities									
	(a) Parenteral compounding items stored to maintain integrity of aseptic environment									
	(b) Adequate refrigerator/freezer capacity to meet storage requirements for all refrigeration-required materials.									
	(c) Shelves and storage containers made of washable, non-porous materials, including non-use of corrugated cardboard/styrofoam									
DIII.4b	The Pharmacy organization maintains adequate and clean compounding areas in compliance with its policies which specify:									
	1) The adequacy of workspace per state regulations									
	2) Frequency, types of cleaning agents and procedures of how work surfaces, equipment and compounding environment are cleaned and disinfected									
	3) Work surfaces are kept free of equipment, supplies, records and other material unrelated to the preparation of a given drug									
	4) Certification of laminar flow hood per organizational policy and/or state/federal regulation									
	5) Validation of cleaning and compounding practice including surface sampling, environmental air sampling and end product sterility testing for pyrogens.									
DIII.4c	Storage of the final pharmaceutical product is in accordance with acceptable professional/community standards of practice which are supported by reference data, including temperature, light and length of time.									
DIII.4d	Areas for compounding of sterile products are functionally separate from areas for the preparation of non-sterile products and are constructed to minimize opportunities for contamination of products.									

EVIDENCE GUIDELINES	CITATION STATEMENTS
D = Documentation S = Survey O = Observation I = Interview D&O: Observation of injectible drug work areas and review of end product testing results validate compliance with the specifications designated in elements 1-3. (DIII.4e) D: Documentation of semi-annual inspections and pre-filter changes as required is available. (DIII.4f) D: Certification reports from the most current three year period are available. (DIII.4f) I & O: Pharmacy personnel are knowledgeable of and use appropriate techniques when using a hood or cabinet. (DIII.4g). I&O: Interviews with staff and observation of practice confirms compliance with policies. (DIII.4h, DIII.4i, DIII.4j) D: Written policies specify elements 1-5. (DIII.4k) O: Products are shipped in compliance with the pharmacy's policy. (DIII.4k)	

	PHARMACY STANDARDS	Prior Visit NM	SS	Current Visit						COMMENTS
				NA	Met	Com	NM	RA	Rec	
DIII.4e	There are adequate work areas for the preparation and manipulation of injectable drugs, which includes the following:									
	1) Methods for inspecting ingredients and final products for the presence of inappropriate particulate matter or signs of deterioration or microbial contamination									
	2) Use of laminar flow hoods									
	3) Use of Class II Biological Safety Cabinets for the preparation of cytotoxic drugs									
DIII.4f	Laminar Flow Hoods and Class II Biological safety cabinets are inspected at least every six months and certified by an independent agency that they are operating according to specifications. Certification records are retained for a minimum of three years.									
DIII.4g	Pharmacy personnel using a laminar flow hood or a Class II Biological safety cabinet use proper techniques consistent with professional standards of practice to ensure a continuous aseptic environment during the admixing of sterile pharmaceuticals.									
DIII.4h	Preparation of injectables from sterile solutions includes the use of filters when removing solutions from ampules.									
DIII.4i	Injectables prepared from non-sterile powders are:									
	1) Dissolved in sterile solution for injection									
	2) Filtered through a 0.2 micron filter.									
DIII.4j	Respiratory medications prepared from non-sterile powders are prepared in an ISO 5 environment and are:									
	1) Dissolved in sterile solution									
	2) Filtered through a 0.2 micron filter									
	3) Packaged under ISO 5 environment conditions									
	4) Periodically end product tested									
DIII.4k	Adequate shipping containers and shipping processes are used in accordance with regulations and manufacturers guidelines to assure drug stability and potency which includes the following:									
	1) Assurance of stability and potency of the products being shipped									
	2) Temperature control									
	3) Non-exposure to light									

EVIDENCE GUIDELINES	CITATION STATEMENTS
D = Documentation S = Survey O = Observation I = Interview	
O: Client service areas are private, clean, safe and in compliance with ADA regulations. (DIII.4l)	
D: External databases are available and used for comparison. (DIII.5a)	
D: Benchmark reports are available. (DIII.5b)	
Note: Organizations may use internal standards, professional standards of practice guidelines, research findings or professional references to determine benchmarks. *Organizations may use multiple sites, divisions and/or professional reference data to benchmark against.*	

	PHARMACY STANDARDS	Prior Visit NM	SS	Current Visit						COMMENTS
				NA	Met	Com	NM	RA	Rec	
	4) Non-exposure to contaminants									
	5) Packaging of medications in a tamper evident manner									
DIII.4l	The organization's physical facilities provide a safe environment for staff and clients and allow for the efficient provision of services.									
	1) Space and privacy are adequate for the services being provided									
	2) Physical facilities and resources permit effective and efficient function of the personnel									
	3) Provisions are made to accommodate clients and staff with disabilities									
DIII.5	An effective and efficient management information system is utilized to ensure accountability at all levels of the organization.									
DIII.5a	When available, the organization uses external databases that provide information relevant to the organization's products and services and creates a basis for comparative analysis.									
DIII.5b	The organization participates in a benchmarking system.									
	1) Benchmark data are consistent with organizationally defined goals and objectives									
	2) Benchmark collected data, when available, are measured against data from other organizations									

EVIDENCE GUIDELINES	CITATION STATEMENTS
D = Documentation S = Survey O = Observation I = Interview	
D: The pharmacy operational plan is available. (DIV.1a)	
D: Governing Body meeting minutes document approval of the initial pharmacy operational plan and changes. (DIV.1b)	
D: An annual evaluation of the pharmacy organization's program and operations is conducted. (DIV.2)	
I: Management describes the annual evaluation process and the way it is used for future planning for the organization. (DIV.2a)	
I: Management personnel describe how the complexity of the organization relates to data collection and utilization. (CIV.2b)	
D & I: Evidence exists that product and service pricing is routinely evaluated. (DIV.2c)	
D: The interrelationship between the pharmacy program evaluation and the overall organizational evaluation is evident when the pharmacy is part of a larger organization. (DIV.2d)	
O: Innovations have been developed and implemented. (DIV.3)	

	PHARMACY STANDARDS	Prior Visit NM	SS	Current Visit						COMMENTS
				NA	Met	Com	NM	RA	Rec	
DIV.	LONG TERM VIABILITY									
DIV.1	Operational planning reflects the Pharmacy's mission.									
DIV.1a	The planning process focuses on performance expectations and is consistent with organizational needs.									
DIV.1b	The written plan is developed, and the initial plan and changes are approved by the governing body.									
DIV.2	An annual systematic evaluation of major aspects of the Pharmacy Organization's program and operations provides the basis for future planning.									
DIV.2a	Mechanisms are established in writing for the collection, dissemination and use of information for the purpose of management, quality improvement, planning and future evaluation purposes.									
DIV.2b	Data appropriate to the complexity and scope of the Pharmacy organization is collected and monitored.									
DIV.2c	Pricing of products and services is routinely evaluated.									
DIV.2d	Results of the Pharmacy organization's evaluation findings are integrated into the corporate organization's report, if applicable.									
DIV.3	The Pharmacy Organization management team fosters innovation within the organization and brings strong leadership to industry-related activities.									
DIV.3a	A common and futuristic vision of the organization is established and sustained.									
	1) A learning environment for all staff is promoted and supported									
	2) Staff development is encouraged									
	3) Governing body members have expertise specific to the enhancement of the organization's mission									
DIV.3b	An atmosphere of mutual respect permeates the organization throughout.									
	1) Interaction between staff, administration and governing body is evident and is facilitated									
DIV.3c	The organization has positioned itself to participate in public forums that shape health care policy and educate consumers.									
DIV.3d	The organization actively networks with other providers and provider organizations.									

COMMUNITY HEAL .ACCREDITATION PROGRAM, INC.
"CHAP"
BOARD OF REVIEW SUMMARY

Board of Review Action Summary

I. Meeting Date:_____
Agency Name:
Address:
Date of Site Visit _____

Type of Visit:
___Initial visit with ss
__Annual, 1st yr. of cycle w/SS
__Yr. 2, __Yr. 3
__Focus __Complaint f/u

Reports
Progress Yes____ No____
Due Date

Complaint Resolved
Yes__ No__

Additional Action Req'd
Yes_____ No_____
Describe

II. Category	I Str.& Function		II Quality		III Resources		IV LT Viability		V. Comments
Standards	# C	# R/A	# C	# R/A	# C	# R/A	#C	#R/A	
Core									
Home Health									
Hospice									
Pvt. Duty									
Home Inf.									
Public Health									
HME									
Pharmacy									
Community Nsg.									
Supp. Staffing									
Totals									

III. Medicare Deficiencies: ___(yes)___(no)

G - Tags: N =__ _____

G - Tag # s.	Description

L - Tags: N = _____

L - Tag #	Description

Legend:
SS: Self Study
C: Commendation
R : Recommendation
R/A Required Action

Orig. (3/98)
Rev.(12/98)
Rev. (6/99)
Rev. (3/00)
Rev. (5/00)
Rev. (1/05)

Board of Review Action Summary: *cont'd.*

Meeting Date:_____
Agency Name:_____

Final Board Decision

___ Progress Report (*as applicable*) ___ *accepted* ___ *not accepted*
___ Accreditation without Required Actions
___ Accreditation with Required Actions
___ Accreditation with Required Actions &
Progress Report due:__30, __ 60, __ 90, __ 120 days
___ Accreditation With Required Actions,
Focus visit in ___30, ___60, ____90, ____120 days
___ Defer Accreditation (*initial accreditation only)*
___ Formal Warning (*continued accreditation only)*
___ Deny Accreditation (*initial accreditation only)*
___ Withdrawal of Accreditation (*continued accreditation only)*

Progress Report Items to be addressed

NEXT VISIT:

_____ Focus Visit
_____ 12 months
_____ 18 months
_____ Contract Cycle

Former Required Actions Met _____

Former Required Actions Continuing _____

Reviewer's Signature _____

Orig. (3/98)
Rev.(12/98)
Rev. (6/99)
Rev. (3/00)
Rev. (5/00)
Rev. (1/05)

Community Health Accreditation Program, Inc.
1300 19th Street NW, Suite 150 Washington, DC 20036 t: 202-862-3413 f: 202-862-3419 web: www.chapinc.org

Accreditation Site Visit Report

Name of Organization:

Address:

Legal Structure:

Services Accredited:

Provider #s:

Principals:

Telephone #:
Fax #:
Email #

Site Visit Date(s):

Site Visitors:

Accreditation Status:

Board of Review Dates: February 9 – 10, 2006

Site Visitor Recommendation:

Board of Review Determination:

SUMMARY

ORGANIZATIONAL STRENGTHS

ORGANIZATIONAL CHALLENGES

COMMENDATION (S) N=

DEFINITION: A statement that indicates an organization has EXCEEDED the requirements of a specific standard.

RECOMMENDATION (S) N=

DEFINITION: A statement that identifies a potential problem with a given standard that may increase in scope and severity if not addressed. A recommendation should be given serious consideration by the Agency, but changes are not mandatory.

REQUIRED ACTION (S) N=

DEFINITION: A statement that indicated non-compliance with CHAP Standards or Criterion.

REQUIRED ACTION (S) NOW MET=